UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FILED UNDER SEAL
PURSUANT TO 31U.S.C. §3730

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF COLORADO, THE STATE OF CONNECTICUT, THE STATE OF DELAWARE, THE STATE OF FLORIDA, THE STATE OF GEORGIA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF IOWA, THE STATE OF LOUSIANA, THE STATE OF MARYLAND, THE STATE OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF MINNESOTA, THE STATE OF MONTANA, THE STATE OF NEVADA, THE STATE OF NEW HAMPSHIRE, THE STATE OF NEW JERSEY, THE STATE OF NEW MEXICO, THE STATE OF NEW YORK, THE STATE OF NORTH CAROLINA, THE STATE OF OKLAHOMA, THE STATE OF RHODE ISLAND, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE STATE OF VIRGINIA, THE STATE OF WASHINGTON, THE STATE OF WISCONSIN AND THE DISTRICT OF COLUMBIA, *ex rel.* JOHN R. BORZILLERI, M.D. Plaintiffs, ABBVIE, INC., AMGEN, INC., BRISTOL-MYERS SQUIBB COMPANY, JOHNSON & JOHNSON, ELI LILLY & COMPANY, NOVARTIS AG, PFIZER, INC., SANOFI S.A., UCB GROUP S.A., EXPRESS SCRIPTS HOLDING COMPANY, CVS CAREMARK CORPORATION, UNITEDHEALTH GROUP, INC., HUMANA, INC., ANTHEM (FORMERLY WELLPOINT), INC., CIGNA CORPORATION, AETNA, INC. AND WELLCARE HEALTH PLANS, INC. Defendants.	CIVIL ACTION NO. RELATOR'S COMPLAINT PURSUANT TO THE FEDERAL FALSE CLAIMS ACT [31 U.S.C.§3729 *et seq.];* AND SUPPLEMENTAL STATE FALSE CLAIMS ACTS **JURY TRIAL DEMANDED**

RELATOR'S COMPLAINT

NATURE OF THE ACTION

1. John R. Borzilleri, M.D. ("Relator"), a physician and professional healthcare investment fund manager, brings this Qui Tam action on behalf of the United States, the State of California, the State of Colorado, the State of Connecticut, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Iowa, the State of Louisiana, the State of Maryland, the State of Massachusetts, the State of Michigan, the State of Minnesota, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Jersey, the State of New Mexico, the State of New York, the State of North Carolina, the State of Oklahoma, the State of Rhode Island, the State of Tennessee, the State of Texas, the State of Virginia, the State of Wisconsin, the State of Washington and the District of Columbia (the "Plaintiff States" and collectively with the United States, the "Government Plaintiffs"), for violations of the Federal False Claims Act, 31 U.S.C. §3729-33 ("FCA") et seq., as well as for violations of the following State False Claims Acts: the California False Claims Act, Cal Government Code §§12650 et seq.; the Colorado Medicaid False Claims Act, Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310; the Connecticut False Claims Act, Conn. Gen. Stat. §17b-301b; the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§1201 et seq.; the Florida False Claims Act, Fla. Stat. §§ 68.081 et seq.; the Georgia False Medicaid Claims Act, Ga. Code Ann. §§49-4-168 et seq.; Hawaii False Claims Act, Haw. Rev. Stat. §§661-21 et seq.; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. Ann. §§175/1 et seq.; the Indiana Whistleblower Reward and Protection Act, Indiana Code §5-11-5.5; the Iowa False Claims Act, Iowa Code §§ 685.1 through 685.7; the Louisiana Medical Assistance Programs Integrity Law, La. R.S. 46:437.1 et seq.; the Maryland False Health Claims Act, MD Code Ann., Health-Gen. § 2-602 (a) (1). (2); the Massachusetts False Claims Act, Mass. Ann. Laws. Ch. 12, §§5A et seq.; the Michigan Medicaid False Claims Act, MCLS §§400.601 et seq.; the Minnesota False Claims Act, Minn. Stat. §§ 15C.01 through 15C.16; the Montana False Claims Act, Mont. Code Anno. §§17-8-401 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§357.010 et seq.; the New Hampshire False Claims Act, RSA tit. XII, Ch. 167:61-b; The New Jersey False Claims Act, N.J. Stat. §2A:32C-1 et seq.; the New Mexico Medicaid False Claims Act,

N.M. Stat. Ann. §§27-14-1 et seq.; the New York False Claims Act, NY CLS St. Fin. §§187 et seq.; the North Carolina False Claims Act, 2009-554 N.C. Sess. Laws §§1-606 et seq.; the Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, § §5053 et seq.; the Rhode Island False Claims Act, R.I. Gen. Laws §§9-1.1-1 et seq.; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§71-5-171 et seq.; the Texas Medicaid Fraud Prevention Act, Tex. Hum. Res. Code §§36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code §§8.01-216.1 et seq.; the Washington Medicaid Fraud False Claims Act, Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214; the Wisconsin False Claims for Medical Assistance Act, Wis. Stats. §§20.931; and the District of Columbia False Claims Act, D.C. Code Ann. §§2-308.03 et seq. (hereafter referred to as the "State False Claims Acts") to recover all damages, civil penalties and all other recoveries provided for under the Federal False Claims Act and the State False Claims Acts against the following Defendants, and their affiliates, subsidiaries, agents, successors and assigns: AbbVie, Inc., Bristol-Myers Squibb Company, Johnson & Johnson, Eli Lilly and Company, Novartis AG, Pfizer, Inc., Sanofi S.A., UCB Group S.A. (hereafter referred to collectively as the *"Manufacturer Defendants"*); as well as Express Scripts Holding Company, CVS Caremark Corporation, UnitedHealth Group, Inc., Humana, Inc., Anthem, Inc. (formerly Wellpoint, Inc.), Cigna Corporation, Aetna, Inc. and Wellcare Health Plans, Inc. (hereafter referred to as the *"Pharmacy Benefit Manager (PBM) Defendants"*).

FRAUD ALLEGATIONS

2. The Relator, John R. Borzilleri, M.D., avers that the Manufacturer Defendants have made fraudulent overpayments of *"Bona Fide Service Fees"* (BFSFs) far in excess of legally-required *"Fair Market Value"* (FMV) to the PBM Defendants, as part of a nationwide systemic collusive price-inflation scheme in the Medicare Part D program. Driven by the fraudulent BFSF scheme, the Manufacturer and PBM Defendants are knowingly utilizing fraudulently-inflated Average Wholesale Prices ("AWP") for the Manufacturer Defendant drugs as the basis for "*negotiated prices"* submitted for payment to the Centers for Medicare & Medicaid (CMS) in Prescription Drug Event ("PDE") reports. Both Manufacturer and PBM Defendants are in clear violation of the False Claims Act and Anti-Kickback Statute.

3. The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which established the Part D drug benefit, depends upon private competition, rather than government mandate, to control drug costs and prevent severe price increases. Section 1860D-11 (the *"noninterference"* provision) of MMA expressly forbids the Secretary of Health and Human Services (HHS) from negotiating directly with pharmaceutical manufacturers for the price of prescription drugs *("negotiated prices*") on behalf of Medicare beneficiaries. With this statutory provision, the Relator does not allege that severe Part D Manufacturer Defendant brand drug price increases are, in and of themselves, fraudulent. Rather, fraudulent BFSFs far in excess of FMV paid to the PBM Defendants have been the causal factor driving the fraudulent drug price increases for the Manufacturer Defendant products.

4. In Part D, plan sponsors (or their PBM surrogates) are expected to *"negotiate"* in good faith with pharmaceutical manufacturers, to attain drug rebates and favorable prices on behalf of Medicare beneficiaries. Rather than honoring their legal commitment to the program, the Manufacturer and PBM Defendants entered into a long-standing, mutually-beneficial financial scheme based upon BFSFs, resulting in severe fraudulent escalation of Part D drug prices and costs. In Part D, the PBM Defendants serve the combine functions of plan sponsor, PBM and specialty pharmacy for approximately 80% of beneficiaries, creating severe conflicts of interest and limiting transparency, which serve to enhance the largely secretive BFSF-based drug pricing scheme.

5. BFSFs are payments from drug manufacturers to PBMs and other service vendors in Part D (and other government drug programs) for a wide array of *"services"*, such as rebate administration, inventory, drug shipping/delivery, reimbursement/financial assistance, patient education/clinical programs, phone support, data reports, etc. In sharp contrast to drug rebates, BFSF's are excluded from Part D *"negotiated price"* calculations, thus leading to higher drug reimbursement prices and greater manufacturer revenues/profits.

6. Based upon his investigation, the Relator has determined that the vast majority of legitimate patient and product support-related BFSFs paid by the Manufacturer Defendants to the PBM Defendants in Medicare

Part D should be based upon drug and patient utilization. This determination is consistent with the Code of Federal Regulations (CFR) governing BFSFs in Medicare Part D that can be found at Sections §423.514 and §423.514. Under *"Reporting requirements for pharmacy benefit manager data"*, the regulations state: *"Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan"*. (Emphasis added)

7. Rather than linking BFSF payments to drug/patient utilization and legitimate FMV assessment, both the Manufacturer and PBM Defendant parties have violated the False Claims Act and the Anti-Kickback Statute, with escalating BFSF payments in Part D based primarily upon massive, anti-competitive price increases. The Manufacturer Defendants have primarily paid the PBM Defendants escalated fraudulent BFSFs based upon "*percent of revenue"* service contracts inclusive of the massive price increases.

8. PBM contract disclosures and insider commentary imply that PBM service fee contracts with drug manufacturers typically fall in the *"3-6 percent of product revenue range"*, without any downward rate adjustment even with severe drug price increases. However, industry commentary and Relator investigation indicate the PBM service fee contract rates can be significantly higher in crowded brand therapeutic categories where the large PBM Defendants typically have considerable negotiating leverage. The Relator uses a conservative *"4% of revenue"* BFSF contract rate estimate in his product fraud estimates for this case.

9. This long-standing, centralized fraudulent pricing scheme, which evidence indicates began from the outset of Medicare Part D, originated from the unique financial incentives regarding rebates and BFSFs incorporated into the program. In Part D, all rebates and discounts provided by drug manufacturer are included in "*negotiate prices"* and serve to lower program and beneficiary drug costs. In sharp contrast, BFSFs are the only major financial item excluded from *"negotiated price"* determinations in Part D. As

such, by paying compensation to the PBM Defendants via BFSFs, rather than rebates as was intended by the Part D law and regulations, while massively increasing drug prices in Part D, the Manufacturer Defendants reap fraudulent product sales in Medicare Part D.

10. The PBM Defendants, in turn, receive escalating BFSFs as *"kickbacks"* for favorable Manufacturer Defendant drug inclusion/handling in Part D drug formularies and the avoidance of long-established, effective, PBM cost-saving strategies (aggressive rebate negotiations, brand drug *"therapeutic substitution"* programs, etc.)

11. CMS places no restrictions on the amount of BFSFs in Part D and initially placed no BFSF reporting requirements on manufacturers and PBMs. Without proper regulatory controls, nor Part D protection from drug price inflation (unlike with Medicaid), the Defendant parties have advanced this BFSF scheme to a staggering magnitude in the first 10 years of the program's existence.

12. The Relator has determined that the majority of PBM Defendant compensation in Medicare Part D has been driven by fraudulent BFSFs linked to massive drug price increases, rather than *"retained"* negotiated manufacturer rebates as was anticipated by Congress and CMS when Part D was enacted.

13. Despite moderating and in some cases declining patient use, all the Manufacturer Defendant drugs implicated in this complaint have exhibited 3-5 fold price inflation in Part D since the 2006 start of the program. For the Manufacturer Defendant products, this severe price inflation has occurred despite moderating and/or eroding patient utilization as indicated by documented US prescription trends. Furthermore, this severe price inflation has occurred uniformly among products in major US drug categories (multiple sclerosis, anti-inflammatory drugs, cancer and diabetes, etc.) crowded with numerous similar therapeutic options. In a properly functioning Part D program, legitimate PBM negotiation with manufacturers on behalf of beneficiaries would have prevented most, if not all, of the severe drug price increases.

14. By the Relator's estimation, this systemic BFSF-related drug pricing scheme represents the largest fraud ever committed in the Medicare program by a wide margin. For the 17 Manufacturer Defendant products targeted in this complaint, the Relator estimates that $18.7 billion of fraudulent Part D drug sales have been enabled by the BFSF pricing scheme between 2006 and 2014, with the fraud ongoing and escalating.

15. The absolute financial impact of the fraudulent pricing scheme has been most severe for many long-marketed, high-cost specialty drugs, which have been the primary driver of US drug spending in recent years. According to PBM Catamaran (now part of PBM Defendant UnitedHealth Group), specialty drugs will account for 31% of US drug costs in 2015, but drive 75% of spending growth between 2011 and 2015. The Relator has determined that the majority of US specialty drug spending growth has been driven by fraudulent price inflation of long-marketed drugs catalyzed by the Part D BFSF financial incentives, rather than new product introductions. The PBM Defendants routinely state that specialty drugs are expected to account for 50% of US drug spending by 2018, with ongoing severe price inflation as a key driver.

16. The BFSF fraud among high-cost specialty drugs has been exacerbated by the increasing dominance of PBM Defendant centralized mail order specialty pharmacies. While the *"Any Willing Pharmacy"* (CFR at §423.120 (a) (8)) provision prohibits rote exclusion of independent pharmacies from Part D networks, CMS regulations do allow the PBM Defendants to offer *"preferred"* financial terms to their wholly-owned specialty pharmacies. These dynamics have led to increased concentration of US specialty drug volume among the PBM Defendants, further decreasing transparency regarding Manufacturer/PBM Defendant financial transactions. Within these wholly-owned specialty pharmacies, the PBM Defendants have proprietary visibility/discretion over all pharmaceutical transactions, while limiting transparency for CMS and private payers. This unique position likely provides the PBM Defendants with numerous pathways to obscure the fraudulent BFSFs and other financial transactions with the Manufacturer Defendants. In this systemic scheme, in recent years, centralized specialty pharmacies are increasingly being employed for a wide array of specialty and traditional brand drugs.

17. Centralized specialty pharmacies, dominated by the PBM Defendants, now account for the majority of the prescription volume for the large-spending specialty drug categories targeted for severe BFSF fraud in the Relator's Qui Tam filings. According to IMS, 86% of multiple sclerosis drug prescriptions were dispensed by specialty pharmacies in 2014, up from 73% in 2010. In the anti-TNF inflammatory drug category, 76% of prescriptions were dispensed by specialty pharmacies in early 2015, up from 54% in 2009. In the oral chronic myeloid leukemia (CML, cancer) category, 70% of prescriptions were dispensed by specialty pharmacies in 2014, up from 49% in 2009.

18. The Relator has determined that the large majority of PBM Defendant financial arrangements, including service fee contracts with drug manufacturers, are based upon the Average Wholesale Prices (AWP) or the related Wholesale Acquisition Cost (WAC), routinely inclusive of price increases. AWP is the standard reference price for reimbursement and payer drug costs in Part D and the private insurance sector. Pertaining to the PBM Defendants, independent pharmacies are routinely reimbursed at a *"discount to AWP"*. Similarly, both CMS and private PBM clients are typically billed drug costs at a *"discount to AWP"*. AWP prices are set by manufacturers and publicly-listed in numerous databases, which are updated in real-time for any manufacturer price increases. In this complaint, the relator references the Redbook/Truven Analytic on-line database, but the same data is available from Medispan, PriceRx and other sources.

19. The WAC price represents the price commonly paid by wholesalers for manufacturer products. WAC is typically 15-20% less than the widely-disseminated AWP at any given time point and rises in lockstep with AWP price increases. PBM Defendant drug acquisition prices from manufacturers are not publicly-disclosed, but may often include price concessions beyond WAC.

20. The Relator's review of public PBM client contracts uniformly indicates that manufacturer/PBM service fee arrangements are based upon AWP. However, manufacturer commentary later in the complaint indicates service contracts based upon WAC. In the Relator's view, the BFSF fraud is severe with either AWP or WAC-based service fee contracts. Both pricing metrics for the Manufacturer Defendant products have fraudulently escalated in the same manner due to the BFSF scheme. Furthermore, neither AWP nor WAC

prices include manufacturer rebates/discounts, thereby further increasing fraudulent Manufacturer Defendant BFSF payments to the PBM Defendants based on *"percent of revenue"* arrangements. *Academy of Managed Care Pharmacy, Pharmacy Payment Methods, 2013 update, page 6.* In this complaint, the Relator uses AWP prices in his analysis due to the wide availability of both historic and current pricing data. By comparison, historic WAC prices are less readily available. For instance, in the Redbook on-line database, only the current WAC price is published. For virtually all the Manufacturer Defendant products, the current Redbook WAC price is listed as an apparently standard 17% discount to the current AWP.

21. Public disclosures from the PBM Defendants indicate the central role of AWP in their financial transactions. As per PBM Defendant CVS Caremark's 2014 10-K on file with the Securities and Exchange Commission (SEC): *"It is possible that the pharmaceutical industry or regulators may evaluate and/or develop an alternative pricing reference to replace Average Wholesale Price ("AWP"), which is the pricing reference used for many of our PBM client contracts, pharmaceutical purchase agreements, retail network contracts, specialty payor agreements and other contracts with third party payors in connection with the reimbursement of drug payments."* As per the 2014 Annual report for PBM Catamaran Corporation (now part of PBM Defendant UnitedHealth Group): *"Average wholesale price, or AWP, is a standard pricing metric published by third-party data sources and currently used throughout the PBM industry as the basis for determining drug pricing under contracts with clients, pharmacies, and pharmaceutical manufacturers."*

22. In addition, AWP is the standard basis for brand drug *"negotiated prices"* submitted for payment by the PBM Defendants to CMS in PDE reports, which are required for each and every Part D prescription. The PDE record is a summary record of all the transactions that occurred surrounding the dispensing event. The plan sponsor (or its contracted PBM) is responsible for creating the record, maintaining an audit trail of PDE source data, and electronically submitting information to CMS.

23. As per CMS Part D regulations, the *"negotiated price"* includes two main elements: 1) the *"ingredient cost"* paid to the pharmacy for the drug itself, and 2) the dispensing fees paid to the pharmacy. In Part D, dispensing fees are minimal ($2-3 per prescription) relative to the *"ingredient cost"* for brand drugs, especially for

extreme-priced specialty drugs. As per the US Department of Health and Human Services (HHS), the "*negotiated price that the sponsors and beneficiaries pay pharmacies for the ingredient cost of the drug is usually based upon Average Wholesale Price (AWP) discounted by a specified percentage…." Office of Inspector General (OIG), OEI-03-7-00350, Comparing Pharmacy Reimbursement: Medicare Part D to Medicaid, February 2009.*

24. In this ongoing BFSF pricing scheme, the PBM Defendants are knowingly submitting a myriad of false claims in the form of PDE reports to CMS inclusive of fraudulently-escalated *"negotiated"* drug prices. The Manufacturer Defendants have knowingly caused these fraudulent PDE reports to be submitted to CMS due to their clear federal liability regarding the FMV of BFSFs and their direct control of published AWP/WAC prices.

25. Part D *"negotiated prices"* based upon AWP/WAC are continuously updated to include the frequent severe price increases (often several times year) that have become routine for the Manufacturer Defendant products. As per the Code of Federal Regulations ("CFR") at §423.505 (b) (3) & (21), plan sponsors and *"first-tier, downstream and related entities"* (FDRs, i.e., including PBMs and specialty pharmacies) must *"update their prescription drug pricing standards regularly to accurately reflect the market price of acquiring the drug." "These updates must occur not less frequently than once every 7 days, beginning with an initial update on January 1 of each year."* Driven by BFSF arrangements, both Defendant parties garner fraudulent financial gains related to these severe, often frequent, anticompetitive price increases, while passing rising drug costs on to taxpayers and Medicare beneficiaries.

26. The Relator's investigation also indicates a high likelihood of *"sham"* BFSF payments (i.e. FMV equal to zero) from the Manufacturer Defendants to the PBM Defendants for services that are not actually being provided. All the PBM Defendants make extensive claims regarding *"clinical support"* they are providing to physicians and patients, especially regarding specialty drugs. Common clinical support services highlighted by the PBM Defendants include injection training, patient consultations regarding drug

efficacy/safety and input regarding drug selection. However, extensive Relator interviews with specialist physicians uniformly indicate that the vast majority of clinical support services are actually being provided by office medical staff or directly by drug manufacturers, not the PBM Defendants or their affiliated specialty pharmacies.

27. The legal liability of the PBM Defendants, either in their Part D role as plan sponsors or FDRs, has already been established by the Court Order and US Department of Justice Statement of Interest related to another active Qui Tam case, the United States of America, ex. rel. Anthony Spay v. CVS Caremark Corporation. The Spay case also definitively established PDE submissions as a *"claim for payment"*. As per the Spay Court Order: *"The defendants' contracts with the sponsor required them to submit PDEs directly to CMS. Relying on CMS program instructions that stated that PDEs "will enable CMS to make payment," the court held that when the defendants submitted PDEs to CMS they 'clearly' were submitting 'claims' under § 3729(a)(2).'* Also per the Court Order: *"the court ruled that these false statements rendered the claims false because defendants were required by 42 C.F.R. § 423.505(k)(3) to certify that the PDEs submitted to CMS were accurate, complete and truthful, and to acknowledge that the data in the PDEs would be used to obtain federal reimbursement."*

28. The Spay case determination is consistent with the Part D certification requirements regarding *"claims data"* for both plan sponsors and PBM/specialty pharmacy subcontractors. As per *§ 423.505 (3), "The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits….are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based upon best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data ad acknowledge that the claims data will be used for the purposes of Federal reimbursement."*

29. In Part D, CMS makes payments to plan sponsors on a monthly basis through estimated subsidy payments and, where needed, at year-end as a result of the payment reconciliation process. Plan sponsors submit bids annually to CMS to participate in the Part D program. The reconciliation process compares subsidy payments made to plan sponsors throughout the year with the cost data submitted by plan sponsors through PDE records and Direct and Indirect Remuneration (DIR) reports to determine residual payments required by CMS to plan sponsors or plan sponsors to CMS. In DIR reports, plan sponsors are required to report to CMS all manufacturer rebates/discounts, which include any BFSFs in excess of FMV.

30. Similar to *"claims data"*, the Part D regulations require both plan sponsors and PBM/specialty pharmacy subcontractors to *"certify"* regarding bid submissions. As per *§ 423.505 (4), "The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."* In § 423.505 (4), the CFR further states: *"The Chief Executive Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."*

31. Driven by the BFSF pricing scheme, the PBM Defendants (in their dominant, multi-functional roles as plan sponsors, PBMs and specialty pharmacies in Part D) have submitted fraudulent annual Part D plan bids to CMS and received fraudulent reconciliation payments. All three of the major plan sponsor subsidy annual estimates, namely *"Regular, "Low-Income, LIS" and "Reinsurance Subsidies"* have been based upon

fraudulently-elevated Manufacturer Defendant *"negotiated"* brand drug prices driven by BFSF fraud. The PBM Defendants have received fraudulent reconciliation payments from CMS due to escalating Part D LIS and Catastrophic drug costs, also driven by fraudulent BFSF-related severe price inflation. By not disclosing BFSFs in excess of FMV, the PBM Defendants (in their role as plan sponsors) have likely also submitted fraudulent DIR reports to CMS.

32. The regulatory and legal requirements regarding BFSFs provide a clear basis for holding both the Manufacturer and PBM Defendants accountable for the fraud. Part D regulations and legal case precedent have clearly established that all BFSF payments must be paid at *"fair market value"* (FMV) commensurate with an *"arm's length transaction between unrelated parties"*. As per Section §423.514 of the CFR: *"Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug"*.

33. Despite long-standing federal fraud concerns surrounding *"percent of revenues"* arrangements, the Relator does not allege that these Manufacturer/PBM Defendant contract structures are, in and of themselves, fraudulent. Rather, the Part D regulations unequivocally require that these fees be paid for legitimate *"bona fide"* services at fair market value (FMV). The Relator has further concluded that *"percent of revenue"* BFSF contracts linked to massive price increases fall outside the protection provided by either the *"Group Purchasing Organization (GPO)"* or the *"Personal Services and Management Contracts"* Safe Harbors. *§1001.952*. These Safe Harbors require both FMV compensation and detailed disclosure to both CMS and private payers. Neither requirement has been met in these typically *"secretive"* BFSF manufacturer/PBM contract arrangements.

34. Prior Department of Justice PBM Defendant case settlements have already established negligence in the FMV of BFSFs as a basis for false claims and kickbacks. On September 7, 2005, a Settlement Agreement

was entered into between the United States, Advanced PCS (now part of PBM Defendant CVS Caremark) and three Relators. In the Settlement, AdvancePCS paid the sum of $137.5 million to resolve allegations brought forth by the US government. As per the Advance PCS Settlement document: *"The United States alleges that…AdvancePCS allegedly solicited and/or received payments of (a) administrative fees from pharmaceutical manufacturers for services related to the negotiation and administration of rebate contracts with those manufacturers. and (b) fees for products and services agreements from pharmaceutical manufacturers…*The settlement document further states: *"The United States also alleges that to the extent that the payments exceeded the value of the above-referenced services and products, AdvancePCS knowingly caused false claims to be made to OPM and false Medicare claims to be made to HHS. In addition, the United States alleges that AdvancePCS knowingly caused false Medicare claims to be made to HHS in connection with soliciting and/or receiving kickbacks in the nature of payments exceeding the value of the above-referenced services and products."*

35. While the majority of the fraudulent drug costs enabled by the Part D BFSF scheme have been borne by US taxpayers at the federal level, state drug spending fraud has also been severe. Prior to 2006, low-income seniors and disabled individuals who qualified for both Medicare and Medicaid received outpatient drug benefits through state Medicaid programs. When Medicare Part D was implemented in 2006, these *"dual eligible"* beneficiaries began receiving drug coverage under Medicare Part D. Due to their compromised health, these *"dual eligibles"* accounted for 50% of Medicaid drug costs and the majority of extreme-priced specialty drug spending prior to the transfer, despite only comprising 13% of the Medicaid enrollment in 2005. *OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011.* By law, each State is required to fund a significant portion of Medicare Part D spending for their respective *"dual eligibles"* via *"clawback payments"* paid to CMS. From 2006 through 2014, States made cumulative *"clawback"* payments of $61.8 billion to CMS. *2015 Medicare Trustees Annual Report, July 2015.*

36. Medicaid requires additional manufacturer rebates for all annual brand price increases greater than inflation

(CPI-Urban) whereas Medicare Part D provides no such protection. After many years of severe price increases, the Medicaid net cost for many brand drugs, especially older specialty drugs, is now a fraction of the Part D price. The Relator filed a separate Qui Tam case specific to multiple sclerosis drugs in January 2014, with an Amended Complaint filed in May 2014. For these prior filings, the Relator obtained propriety information indicating that the Medicaid 2013 net cost for four long-marketed MS specialty therapies was 80-90% below the $40,000-50,000 annual patient cost range in Part D at that time. Similar dynamics now pervade for many other older brand traditional and specialty drugs.

37. In its most recent comparison of Medicaid and Medicare Part D rebates, the Office of Inspector General (OIG) concluded that *"the inflation-based additional rebate, meant to protect Medicaid from large drug increases in drug prices, was the primary reason that Medicaid rebates were higher than Part D rebates... For the 200 brand-name drugs with the highest Part D expenditures in 2012..rebates accounted for 47 percent of Medicaid expenditures, whereas rebates totaled 15 percent of Part D expenditures." OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.*

38. If state *"dual eligibles"* had remained within Medicaid, their brand drug costs would now be a fraction of the cost in Medicare Part D. The Relator alleges that a significant portion of state *"clawback"* payments since the start of Part D have been driven by the BFSF-related fraudulent pricing scheme.

39. The BFSF fraud is systemic, involving the majority of the top-spending drugs in the Part D program. The Relator's investigation indicates that the BFSF and drug pricing fraud has been greatest in the multiple sclerosis category, the top-spending specialty drug category in Part D. In this current complaint, the Relator implicates the next three largest Part D spending categories in which severe BFSF fraud is also apparent; namely anti-tumor necrosis factor (TNF) drugs (for rheumatoid arthritis, etc.), chronic myeloid leukemia (CML) oral cancer drugs and diabetes therapies.

40. Outside of these major therapeutic categories, the Relator also alleges BFSF-related pricing fraud for seven major brand drugs sold by Manufacturer Defendant Pfizer, in which there is a vast divergence between manufacturer-reported US sales and patient utilization trends.

41. The products targeted in this complaint are AbbVie's Humira (anti-TNF); Amgen's Enbrel (anti-TNF); Johnson & Johnson's Simponi (anti-TNF); UCB's Cimzia (anti-TNF); Novartis' Gleevec (CML cancer) and Tasigna (CML cancer); Bristol Myer Squibb's Sprycel (CML cancer); Sanofi's Lantus (insulin for diabetes) and Apidra (insulin for diabetes); Eli Lilly's Humulin (insulin for diabetes); and Pfizer's Lyrica (neurologic pain), Viagra (erectile dysfunction), Celebrex (osteoarthritis/pain), Premarin (hormone replacement/osteoporosis), Pristiq (depression), Chantix (smoking cessation) and Relpax (migraine).

42. The impact of Manufacturer Defendant drug price increases on both overall US drug spending and the Medicare Part D program has been staggering since the 2006 start of the program. To provide a sense of the magnitude, in **Exhibit 1** the Relator compares actual reported 2014 US sales for some of the largest Manufacturer Defendant products with estimated US sales for the same drugs without price increases since the start of Part D (i.e. at 2005 prices). The list includes four of the top ten spending drugs in Medicare Part D, namely Humira, Enbrel, Gleevec and Lantus. Overall, price increases since the start of Part D accounted for approximately $13.9 billion or 56% of Manufacturer Defendant-reported 2014 US revenues of $24.8 billion for these eight drugs. By the Relator's estimation, price increases have accounted for the 82% of the US sales growth these eight Manufacturer Defendant products from the start of Part D through 2014, with the fraud ongoing and accelerating.

43. For AbbVie’s Humira, the largest-selling US drug, price increases accounted for approximately $3.5 billion or 59% of US sales growth between 2005 and 2014. For Amgen’s Enbrel, price increases accounted for approximately $2.5 billion or 101% of 2005-2014 US sales growth. For Sanofi’s Lantus, the highest spending drug in Medicare Part D, price increases accounted for approximately $3.7 billion or 75% of reported 2005-2014 US sales growth. For Novartis’ Gleevec, the second highest spending Part D cancer drug, price

increases accounted for approximately $1.5 billion or 95% of 2005-2014 US sales of $2.1 billion. With severe declines in patient usage/prescription volume, price increases have accounted for far more than all 2005-2014 US sales growth for Pfizer's Viagra and Celebrex, as well as for Eli Lilly's Humulin. With considerable competitive pressures facing all the products targeted in this case, the Relator avers that fraudulent Part D BFSF incentives between the Manufacturer and PBM Defendants have been the driving force behind this severe price inflation.

Exhibit 1
Manufacturer Defendant US Product Sales
2014 Cumulative Impact of Price Increases

	Year of FDA Approval	2005 Reported US Sales ($mil)	2014 Reported US Sales ($mil)	2014 Sales at 2005 Prices ($mil)	2014 Sales due to Price ($mil)	Price as % of 2005-14 Sales Growth (%)
Humira (AbbVie)	**2003**	$560	$6,524	$3,014	$3,510	59%
Enbrel (Amgen)	**1997**	2,470	4,404	2,454	1,950	101%
Gleevec (Novartis)	**2001**	524	2,170	628	1,542	94%
Lantus (Sanofi)	**2000**	846	5,831	2,144	3,686	74%
Humulin (Eli Lilly)	**1982**	411	713	213	500	165%
Lyrica (Pfizer)[1]	**2004**	717	2,315	1,098	1,217	76%
Viagra (Pfizer)	**1998**	796	1,140	449	691	201%
Celebrex (Pfizer)	**1998**	1,577	1,735	951	784	496%
Total		**$7,901**	**$24,832**	**$10,951**	**$13,881**	**82%**

[1] 2006 US Lyrica/Viagra/Celebrex sales, not 2005.

Source: Corporate reports, IMS, Redbook and Relator estimates.

44. Due to modest assumed *"4% of revenue"* service contract rates, the estimated fraudulent Manufacturer Part D drug revenues enabled by this price inflation scheme are magnitudes greater than the direct BFSF payment fraud. For the 17 products in this case, the Relator conservatively estimates $747 million in fraudulent BFSF payments by the Manufacturer Defendants to the PBM Defendants in Medicare Part D through 2014, with the fraud ongoing and escalating. For these same products, the Relator estimates $18.7 billion of fraudulent Part D sales through 2014, with the fraud ongoing and escalating. In **Exhibit 2**, a summary of the 2006-2014 cumulative direct BFSF payment fraud estimates and US Part D drug sales fraud estimates by product is

provided.

Exhibit 2

Cumulative Estimated Part D Fraud Estimates: 2006-2014
Fraudulent BFSF Payments
and Part D Sales Fraud
By Manufacturer Defendant Product
($ million)

	Year of FDA Approval	Therapeutic Category	Estimated Part D % of Product Rxs (%)	Part D BFSF Payment Fraud ($mil)	Part D Sales Fraud ($mil)
Humira (AbbVie)	**2003**	**Anti-TNF**	30%	$135	$3,385
Enbrel (Amgen)	**1997**	**Anti-TNF**	30%	108	2,703
Cimzia (UCB)	**2008**	**Anti-TNF**	30%	7	171
Simponi (Johnson & Johnson)	**2009**	**Anti-TNF**	30%	9	194
Gleevec (Novartis)	**2001**	**CML cancer**	55%	138	3,446
Tasigna (Novartis)	**2007**	**CML cancer**	55%	8	198
Sprycel (Bristol-Myers Squibb)	**2006**	**CML cancer**	55%	21	488
Lantus (Sanofi)	**2000**	**Diabetes**	30%	153	3,816
Apidra (Sanofi)	**2004**	**Diabetes**	30%	2	43
Humulin (Eli Lilly)	**1982**	**Diabetes**	30%	24	536
Lyrica (Pfizer)	**2004**	**Neurologic pain**	30%	47	1,218
Viagra (Pfizer)	**1998**	**Erectile Dysfunction**	10%	13	347
Celebrex (Pfizer)	**1998**	**Osteoarthritis/Pain**	35%	50	1,411
Chantix (Pfizer)	**2006**	**Smoking Cessation**	15%	3	77
Premarin (Pfizer)	**1942**	**Hormone/Osteoporosis**	30%	14	348
Pristiq (Pfizer)	**2008**	**Antidepressant**	25%	6	160
Relpax (Pfizer)	**2002**	**Migraine**	15%	1	32
Total				$747	$18,670

Source: Corporate reports, IMS, Redbook and Relator estimates.

45. The absolute magnitude of Part D sales fraud is particularly severe for long-available specialty drugs with market-leading positions. The magnitude of the sales fraud for these specialty drugs is a reflection of their wide use, high absolute prices and severe price increases over an extended period. The Relator estimates cumulative Part D sales fraud of $3.4 billion and $2.7 billion for the 2006-2014 period for AbbVie's Humira (FDA-approved 2003) and Amgen's Enbrel (FDA-approved 1997), respectively, with the fraud ongoing and accelerating. In the CML cancer space, the Relator estimates cumulative Part D sales fraud of $3.5 billion

for Novartis' Gleevec (FDA-approved 2001) for the 2006-2014 period, with the fraud ongoing and accelerating. High oral cancer drug utilization in Part D (estimated 55% of CML prescriptions) and Gleevec's massive price inflation since the start of the program are driving factors. Among traditional drugs, the estimated Part D sales for Sanofi's long-acting insulin, Lantus (FDA-approved 2000) dwarfs all other products. The Relator estimates cumulative Lantus Part D fraudulent sales of $3.8 billion for the 2006-2014 period, with the fraud ongoing and escalating. With massive price inflation and wide use in the large diabetes segment, Lantus has apparently become the top-spending single Medicare Part D drug in recent years.

46. While the BFSF scheme began with the 2006 start of Part D, the pace of pricing fraud has accelerated in more recent years for the majority of Manufacturer Defendant products targeted in this complaint. In **Exhibit 3**, the Relator provides the divergent US pricing and patient utilization trends for the 2010 to 2015 period. As a direct proxy for US patient utilization, the Relator employs total annual prescriptions for each product, as per the IMS National Prescription Audit (NPA). IMS has long been the standard source of prescription data in the US drug industry. For pricing, the Relator quotes Average Wholesale Prices (AWP), which are set by drug manufacturers and publicly-available via several databases. The Relator obtained the data directly from the Truven Analytic/Redbook database.

47. For the majority of the Manufacturer Defendant drugs, especially for long-marketed category leaders, price inflation has greatly exceeded patient utilization trends. Further indicative of anticompetitive activity, the price inflation has been severe, uniform and lockstep in the anti-TNF, CML cancer and diabetes therapeutic categories. For instance, the annual patient cost of therapy for all four US anti-TNF drugs has nearly doubled from $23-25,000 in 2010 to the $45-50,000 range in 2015, accounting for two-thirds of spending growth in the category.

48. In the CML category, the primary driver of spending has been recent staggering price increases for the market leader, Novartis' Gleevec, despite minimal US prescription growth (2%) since 2010. The AWP annual cost per patient of Gleevec doubled from the start of Part D to the $65,000 range in 2010 and more than doubled

again to the $150,000 range in early 2015. With ongoing severe inflation, in 2015 all three leading CML therapies have annual AWP costs per patient in the $150,000 range.

Exhibit 3

Cumulative AWP Price Inflation Vs. Drug Utilization: 2010-2015

By Manufacturer Defendant Product

	Year of FDA Approval	Therapeutic Category	2010 Annual Patient Cost AWP ($)[1]	2015 Annual Patient Cost AWP ($)[2]	2010-15 % Change in AWP	2010-14 Change in Total US Prescriptions[3]
Humira (AbbVie)	**2003**	**Anti-TNF**	$24,149	$49,753	106%	49%
Enbrel (Amgen)	**1997**	**Anti-TNF**	$25,111	$49,762	98%	2%
Cimzia (UCB)	**2008**	**Anti-TNF**	$22,978	$43,824	91%	54%
Simponi (Johnson & Johnson)	**2009**	**Anti-TNF**	$24,933	$50,396	102%	93%
Gleevec (Novartis)	**2001**	**CML cancer**	$66,991	$147,788	121%	2%
Tasigna (Novartis)	**2007**	**CML cancer**	$115,856	$151,269	31%	268%
Sprycel (Bristol-Myers)	**2006**	**CML cancer**	$115,074	$151,211	31%	155%
Lantus (Sanofi)	**2000**	**Diabetes**	$2,176	$5,442	150%	23%
Apidra (Sanofi)	**2004**	**Diabetes**	$2,038	$4,889	140%	49%
Humulin (Eli Lilly)	**1982**	**Diabetes**	$1,058	$2,641	150%	-28%
Lyrica (Pfizer)	**2004**	**Neurologic pain**	$2,275	$5,063	122%	4%
Viagra (Pfizer)	**1998**	**Erectile Dysfunction**	$979	$2,182	123%	-21%
Celebrex (Pfizer)	**1998**	**Osteoarthritis/Pain**	$1,617	$3,681	128%	-20%
Chantix (Pfizer)	**2006**	**Smoking Cessation**	$1,965	$4,205	114%	-29%
Premarin (Pfizer)	**1942**	**Hormone/Osteoporosis**	$736	$1,587	116%	-41%
Pristiq (Pfizer)	**2008**	**Antidepressant**	$1,643	$3,700	125%	-22%
Relpax (Pfizer)	**2002**	**Migraine**	$1,260	$2,182	73%	-18%

[1] Redbook; 2 FDA-approved maintenance dosing; 3 IMS NPA.

49. In the diabetes category, Sanofi's long-acting insulin, Lantus, has exhibited a 150% AWP price increase between 2010 and 2015, accounting for almost all US product spending growth in recent years. Similar severe price increases have occurred for Sanofi and Eli Lilly's short-acting insulins, Apidra and Humulin, respectively. Humulin's 150% price increase between 2010 and 2015 has occurred despite a 28% decline in prescriptions.

50. Manufacturer Defendant Pfizer's products have exhibited uniform and severe divergence in their pricing and utilization trends. Six of the seven Pfizer products have more than doubled in price between 2010 and 2015, despite six of the seven showing a severe decrease in US prescriptions.

51. The Relator's investigation indicates that the majority of the financial benefit from this accelerating recent price inflation has accrued to the Manufacturer and PBM Defendants. In the Relator's view, severe anti-competitive behavior, enabled by Part D BFSF incentives, is the only viable explanation for these directionally inconsistent pricing and utilization trends for the Manufacturer Defendant drugs.

52. Due to cumulative impact of price increases and accelerating inflation in recent years, the magnitude of BFSF-related fraud continues to escalate with each Part D program year. Due to unique aspects of Medicare Part D, the massive increase in Part D drug costs due to BFSF fraud has primarily been borne by federal and state taxpayers. However, many Part D beneficiaries have also faced severe financial harm and decreased drug access due to onerous cost-sharing requirements related to severe, fraudulent drug price increases.

53. In **Exhibit 4**, the Relator provides the estimated direct BFSF payment fraud for the 17 targeted products by Part D plan year between 2006 and 2014. The Relator estimates that the Manufacturer Defendants paid the PBM Defendants fraudulent BFSFs of $6 million in 2006, rising to $205 million in 2014. The Relator estimates cumulative fraudulent BFSF payments to the PBM Defendants of $747 million between 2006 and 2014, with the fraud ongoing and escalating. These conservative estimates are based upon a stable *"4% of revenue"* BFSF service contract structure between Manufacturer and PBM Defendants. The Relator suspects that discovery will uncover far larger payments to the larger PBM Defendants in many instances due to their considerable negotiating leverage.

Exhibit 4

Estimated Direct Part D BFSF Payment Fraud
By Manufacturer Defendant Product and Year
($ million)

	2006	2007	2008	2009	2010	2011	2012	2013	2014
Humira (AbbVie)	$3	$2	$5	$6	$10	$15	$23	$30	$42
Enbrel (Amgen)	2	3	7	9	11	13	19	21	23
Cimzia (UCB)	-	-	-	0.1	0.3	0.4	1	2	3
Simponi (Johnson & Johnson)	-	-	-	-	0.4	1	1	2	4
Gleevec (Novartis)	1	2	5	8	15	19	24	29	34
Tasigna (Novartis)	-	-	-	0	1	1	1	1	3
Sprycel (Bristol-Myers)	-	0	0	1	1	3	4	5	7
Lantus (Sanofi)	1	3	6	10	13	14	26	35	44
Apidra (Sanofi)	-	-	-	0.1	0.1	0.0	0.1	0.5	1
Humulin (Eli Lilly)	-	0.4	1	1	2	4	4	6	6
Lyrica (Pfizer)	-	0	2	3	4	6	8	11	15
Viagra (Pfizer)	-	0	1	1	2	2	3	3	3
Celebrex (Pfizer)	-	3	4	5	5	7	9	12	11
Chantix (Pfizer)	-	-	-	0	0	0	1	1	1
Premarin (Pfizer)	-	-	-	-	0	1	3	4	5
Pristiq (Pfizer)	-	-	-	0	0	0	1	2	3
Relpax (Pfizer)	-	-	-	-	0	0	0	0	1
Total	$6	$14	$31	$45	$65	$85	$129	$166	$205
Growth	-	-	126%	46%	44%	30%	53%	28%	24%
Cumulative Total	$6	$20	$51	$96	$162	$246	$376	$541	$747

Source: Corporate reports, IMS, Redbook and Relator estimates.

54. In **Exhibit 5**, the Relator provides the estimated, far greater, fraudulent Part D drug sales, enabled by the BFSF scheme, for the 17 products by plan year between 2006 and 2014. The Relator estimates that the Manufacturer Defendants garnered fraudulent Part D sales of $151 million in 2006, rising to $5.1 billion in 2014. The Relator estimates cumulative fraudulent Part D Manufacturer Defendant products sales of $18.7 billion, enabled by the BFSF scheme, with the fraud ongoing and escalating.

Exhibit 5

Estimated Part D Sales Fraud

By Manufacturer Defendant Product and Year

($ million)

	2006	2007	2008	2009	2010	2011	2012	2013	2014
Humira (AbbVie)	$63	$44	$115	$161	$256	$363	$580	$751	$1,053
Enbrel (Amgen)	38	84	177	224	266	322	470	536	585
Cimzia (UCB)	-	-	-	2	7	9	21	46	86
Simponi (Johnson & Johnson)	-	-	-	-	9	18	31	46	90
Gleevec (Novartis)	25	56	127	212	369	469	608	731	848
Tasigna (Novartis)	-	-	-	5	15	24	36	37	82
Sprycel (Bristol-Myers)	-	5	10	20	26	64	92	134	171
Lantus (Sanofi)	24	75	153	243	329	356	662	867	1,106
Apidra (Sanofi)	-	-	-	1	3	1	3	12	22
Humulin (Eli Lilly)	-	9	24	31	52	89	107	138	150
Lyrica (Pfizer)	-	0	47	82	109	140	200	275	365
Viagra (Pfizer	-	7	21	32	42	47	64	65	69
Celebrex (Pfizer)	-	64	105	122	134	163	235	312	274
Premarin (Pfizer)	-	-	-	-	6	11	13	21	26
Pristiq (Pfizer)	-	-	-	-	-	30	79	109	131
Chantix (Pfizer)	-	-	-	-	5	12	30	50	63
Relpax (Pfizer)	-	-	-	-	-	2	8	8	13
Total	$151	$344	$778	$1,135	$1,630	$2,119	$3,237	$4,141	$5,135
Growth	-	128%	126%	46%	44%	30%	53%	28%	24%
Cumulative Total	$151	$495	$1,273	$2,408	$4,038	$6,157	$9,395	$13,535	$18,670

Source: Corporate reports, IMS, Redbook and Relator estimates.

55. Consistent with the BFSF scheme, Part D manufacturer brand drug discount/rebates have been very modest each year during the first decade of the program, despite massive price increases for most brand drugs. According to the Medicare Trustees Reports, Medicare Part D rebates (as a percentage of total program drug costs) were only 8.6% in 2006, with a steady incremental increase to 11.7% in 2012. During the two most recent program years, the rebate rate has increased at a slightly faster pace, reaching 14.4% in 2014. *Annual Report of the Medicare Trustees, July 2015*. The modest recent overall Part D rebate rate increases pale in comparison to accelerating price increases for the majority of products targeted in this complaint. The Relator's investigation, and CMS' own data, indicates that rebates for extreme-priced specialty drugs have

often been far less than the average annual rebate rate in Medicare Part D. *GAO-10-242, Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier, January 2010.* As per this GAO report, the Part D *"negotiated"* discounts for Anti-TNF drugs, AbbVie's Humira and Amgen's Enbrel were only in the 2-8% range for the plan years 2006 through 2008. See **Exhibit 23**. Novartis provided no Part D discounts for its CML therapy, Gleevec, for the plans years 2006 through 2008. With these rebate and pricing trends, the vast majority of the financial benefit from severe Part D brand drug price increases has accrued to manufacturers and PBMs.

56. Central to the BFSF scheme, the PBM Defendants have *"retained"* minimal manufacturer rebates as compensation throughout the history of the Part D program. According to the Office of Inspector General (OIG), PBMs retained less than 1% or only $24 million of $6.5 billion in Part D manufacturer rebates for the plan year 2008. *OIG HHS Report, OEI-02-08-00050, March 2011.* The Relator's investigation further indicates that PBM *"retained"* manufacturer rebates have been minimal throughout the history of Part D. The Relator has determined that largely secretive, fraudulent BFSFs linked to severe price increases, is the principle source of PBM compensation in Part D, since inception of the program.

57. Both external experts and industry insiders confirm that the vast majority of legitimate *"services"* provided for drug manufacturers by PBMs/specialty pharmacies are tied to drug volume and patient usage. For all the drugs targeted in this case, US Manufacturer Defendant-reported sales have greatly exceeded documented patient prescription utilization trends. In some cases, the disparity has been extreme, with sales growth driven by massive price increases, despite declining prescription volume.

58. For the vast majority of "*services*" provided by the PBM Defendants to the Manufacturer Defendants, the legitimate FMV assessment of service fees should incorporate the standard *"Cost Approach".* In the *"Cost Approach"*, appropriate PBM Defendant/specialty pharmacy compensation is determined based upon a straightforward calculation of staff/resource requirements, hourly wages and time per a *"unit"* of service.

59. In the scheme, the Manufacturer Defendants have instead paid and continue to pay the PBM Defendants fraudulent BFSFs, primarily via service contracts based upon a *"Market Approach"* to FMV. In the *"Market Approach"*, FMV is determined based upon comparable arrangements in the industry rather than through a true cost assessment of providing the services. The Relator has determined that the standard *"Market Approach"* utilized by the Defendant parties has been to base service contracts upon a *"percent of revenues"*, inclusive of price increases. In a minority of instances, the Manufacturer and PBM Defendants may be using alternate financial arrangements (lump-sum payments, etc.) for fraudulent BFSF payments.

60. In the BFSF pricing scheme, the Manufacturer Defendants have fraudulently increased AWP/WAC prices, typically in a near uniform manner in the major therapeutic categories targeted in the Relator's Qui Tam cases. The fraudulent vast and frequent price increases lead to an immediate surge in BFSFs to the PBM Defendants paid as a percentage of AWP/WAC. These *"kickbacks"* directly incent the PBM Defendants to use higher cost drugs in the Part D plans they control, to the detriment of beneficiaries and taxpayers.

61. The PBM Defendants (in their dominant role as plan sponsors in Part D) have also submitted fraudulent annual plan bids to CMS. All of the three major plan sponsor subsidy estimates, namely *"Regular, "Low-Income, LIS"* and *"Reinsurance Subsidies"* have been based upon fraudulently-elevated brand drug prices due to BFSF-related fraud. However, the severe Part D pricing fraud has had the greatest impact on skyrocketing *"Reinsurance Subsidy"* payments for the rising number of non-LIS beneficiaries exceeding the modest annual *"Catastrophic"* spending limits. *"Reinsurance Subsidy"* payments, which are 80% covered by the federal government, have increased from $6.0 billion in 2006 to $27.8 billion in 2014, now accounting for 33% of Part D spending.

62. Commensurate with rising *"Catastrophic"* spending, the Relator has determined that the vast expansion of Manufacturer Defendant Patient Assistance Programs (PAPs) in Part D has been essential to enabling the BFSF-enabled severe price inflation, especially for extreme-priced specialty drugs. The Relator also suspects significant fraud related to Manufacturer/PBM economic transfers pertaining to unlimited PBM Defendant/plan sponsor 15% *"Catastrophic"* cost-sharing requirements in Part D.

63. The PBM Defendants (in their role as plan sponsors) have also submitted fraudulent *"Direct and Indirect Remuneration"* (DIR) reports to CMS. In annual DIR reports, Plan sponsors are required to disclose to CMS all manufacturer discounts and rebates, including any amounts retained by the PBM. By law, any BFSFs in excess of FMV must be reported to CMS as price discounts in the annual DIR reports.

64. In Part D, CMS places the legal requirements for FMV determination squarely on drug manufacturers. Manufacturers are required to provide detailed FMV justification of all BFSFs paid, itemized at individual drug and service level, when requested by federal authorities. The PBM Defendants in this case are also in clear violation of both the False Claims Act and the Anti-Kickback Statute due to the legal and regulatory certification requirements for their participation in Part D, both as plan sponsor *"insurance"* entities and in their roles as Pharmacy Benefit Managers (PBMs) and specialty pharmacies (i.e., *"First Tier, Downstream and Related (FDR) entities"*).

65. The Relator uncovered this BFSF fraud scheme through his independent investigation. However, definitive confirmation of the scheme came from his attendance at a one-of-kind conference specifically focused on the topic. On October 7-8, 2013 in Philadelphia, PA, the Relator attended a two-day conference entitled, *"Fair Market Value of Bona Fide Service Fees"*. The conference was attended by a wide array of industry insiders who are directly involved in Part D BFSF contracts. Attendees included manufacturer and PBM/specialty pharmacy corporate staff, as well as the leading legal and FMV consulting firms that advise them. Consistent commentary from insiders at the conference, verified all key components of the fraudulent BFSF arrangements between the Manufacturer and PBM Defendants. Furthermore, all insider presenters at the conference indicated acute awareness of the legal risks posed by potential FMV challenges to the ubiquitous industry-wide practice of structuring BFSF contracts based upon a *"percent of revenue"*, inclusive of large price increases. Detailed commentary from the conference is provided in this complaint.

66. The Relator has determined that escalating systemic BFSF fraud between manufacturers and PBMs in Part D since the program's 2006 start has been the central factor driving severe brand drug price inflation in the

US marketplace relative to many international markets. The role of PBMs in international drug markets is minimal, while the dominant PBM Defendants control access to approximately 80% of lives both in Medicare Part D and in the private domestic drug insurance marketplace. After years of severe anti-competitive price inflation, many long-marketed brand drugs, especially of the specialty variety, now cost 50-75% more in the US compared to many European markets. By comparison, the majority of these brand drugs had parity pricing in the US and Europe prior to the enactment of Medicare Part D.

67. The BFSF fraud in Part D has also been the catalyst for similar systemic service fee fraud and vast drug price inflation in the US private insurance market. From the 2003-2011 SEC financial disclosures of Medco Health (now part of Defendant Express Scripts), the Relator has determined that drug manufacturers and PBMs transitioned from a mutually-dependent manufacturer-rebate driven economic model to a service fee model following the passage/enactment of Medicare Part D and its unique BFSF incentives. This transformation was made intentionally and deceitfully, without disclosure to CMS or private payer clients. To this day, BFSFs, and their central role in Medicare Part D, remain largely unknown other than by corporate insiders and their hired consultants.

68. The Relator's three years of investigation, has not uncovered any other legitimate basis for the severe US drug price inflation, targeted in this complaint, but for the fraud driven by the unique BFSF incentives. None of the Manufacturer Defendants have disclosed viable alternative explanations, such as rising manufacturing drug costs or severe drug shortages. In addition, there is no viable economic rationale for the widening cost disparity for many older specialty drugs in the US compared to international markets.

69. The Relator also found no evidence that any of the Manufacturer Defendant products have required a substantial increase in legitimate support services outside of those linked to drug utilization. For the long-marketed drugs in this complaint, there has been little change in the true nature of PBM Defendant *"services"* provided since the start of Part D, ironically other than a vast expansion of financial assistance necessitated by severe drug price inflation. As such, the increased BFSFs have been fraudulently-driven primarily by

price increases, not a legitimate increase in service needs.

70. In a normally operating marketplace, the Manufacturer Defendant drugs should have faced severe pricing pressure due to escalating competitive pressures. Contrary to any competitive market rationale, the Manufacturer Defendants instituted massive, lock-step price increases in order to preserve and grow US product revenues despite slowing or deteriorating patient usage trends. Further indicative of *"collusive or cooperative"* pricing dynamics, the massive price increases and pricing levels have been nearly uniform in many therapeutic categories, including the large multiple sclerosis, inflammatory and diabetes areas.

71. The drug price increases have counter-intuitively also accelerated across many therapeutic categories as new product competition entered the market. The Relator alleges that these pricing dynamics would not have been possible without the Manufacturer Defendants providing escalating fraudulent BFSF compensation to the PBM Defendants which dominate the Part D program.

72. The Relator has also determined that systemic BFSF fraud in Part D has been the primary driver of the severe launch price levels for many new drugs entering the US market in recent years. The fraud is most apparent in therapeutic categories crowded with numerous similar drug therapies, including the multiple sclerosis, ant-inflammatory (e.g., rheumatoid arthritis), diabetes and Chronic Myeloid Leukemia (CML) oral cancer categories. In all these major Part D therapeutic categories, massive fraudulent inflation of long-marketed drugs has provided a new higher pricing plateau for new drugs entering the category. In certain cases, as with Biogen in the MS category and Sanofi in the insulin diabetes category, the fraudulent inflation of a given Defendant's older drug has provided a fraudulent higher pricing plateau for its new product entering the US market. In the MS market, the massive fraudulent inflation of Biogen's Avonex (from $15,000/patient/year in 2005 to the $55,000/patient/year range in 2013) despite eroding patient usage allowed the company to claim that its new oral drug, Tecfidara, was launched at a *"modest discount*" at $53,000/patient in 2013. Similarly, in the insulin diabetes segment, Defendant Sanofi launched its similar long-acting insulin formulation, Toujeo, in February 2015 at the same price as Lantus, following massive fraudulent inflation of

the latter. Toujeo is just a more concentrated version of Lantus. Despite eroding volume, the AWP price of Lantus has increased 68% just since the start of 2013.

73. In this complaint, the Relator estimates fraudulent BFSF payments and fraudulent Part D drug sales based upon manufacturer-reported US sales. Since contractual PBM Defendant BFSFs are primarily based upon AWP prices, the Relator's estimates likely underestimate the magnitude of the direct Part D BFSF payment fraud in most instances.

74. In the Relator's view, two related structural factors in Part D have greatly enhanced and accelerated BFSF fraud in the program. First, the Part D regulations allow all major drug benefit functions, including plan sponsor, PBM and specialty pharmacy to be provided under the same ownership structure. This regulatory deficiency appears to have greatly undermined the proper functioning of Part D by creating severe conflicts of interests. In Part D, CMS depends significantly upon voluntary plan sponsor cooperation for preventing/detecting fraud in the program, including oversight of PBM and specialty pharmacy activities.

75. Second, the lack of Part D functional restrictions has contributed to severe and ongoing consolidation in the PBM/specialty pharmacy industries, as well in the Part D program itself. At present, approximately 80% of beneficiaries are enrolled in Part D plans in which all three primary benefit functions were provided by fully-integrated PBM Defendants and/or closely-affiliated parties. Accelerating concentration in the broader PBM and specialty pharmacy markets has also likely increased BFSF-related pricing fraud in Part D. Most notably, the Relator has noted a marked acceleration in anti-competitive pricing activity since the April 2012 merger of Express Scripts and Medco, the two former largest independent US PBMs.

76. For clear and specific reasons, the Relator has decided to file this second Qui Tam case in a separate US Federal District Court from the initial one targeting the multiple sclerosis market. First, the Relator is resolute that the BFSF fraud outlined in this complaint is systemic in nature and long-standing since the 2006 start of Medicare Part D. Many US drug therapies may ultimately be implicated in this BFSF scheme. Due to legal and financial complexities, as well as limited Defendant transparency, the investigation of each case may be

quite unique. As such, in the Relator's view, the government's intervention decision regarding a particular drug or drug category may have limited bearing on other investigations. In discussions regarding the pending Qui Tam case, the Relator and counsel were informed by federal prosecutors that their investigation would remain solely focused on the multiple sclerosis area regardless of other potential case filings. As such, the Relator and legal counsel concluded that filing this additional case in an alternate Federal District court was advisable. Both the Relator and legal counsel remain available to assist federal authorities in any way with either of these Qui Tam cases.

77. The Relator has noted common characteristics among the Manufacturer Defendant drugs associated with the greatest US price inflation-related fraud. First, the products are typically either the largest absolute US revenue-generating products and/or among the largest US growth drivers for the respective Manufacturer Defendant. For instance, AbbVie's Humira accounted for 65% the company's 2014 US revenues and a far greater share of its US revenue growth and profits. Similarly, Sanofi's Lantus accounted for 45% of the company's US 2014 revenues and the majority of its recent US growth. Second, the products are mostly long-marketed drugs that were established therapeutic category leaders at the outset of the Part D drug program. With the unique Part D BFSF incentives and the program's lack of price restraint, both Defendant parties were financially-incented to maximize incumbent product revenue and profitability, rather than seek aggressive discounts from newcomers in major therapeutic categories.

78. Vastly escalating fraudulent BFSFs tied to massive price increases, for established market-leading products, offered the PBM Defendants far greater revenues/profits as compared to gains from aggressive negotiations for rebates with manufacturers. At stable *"percent of revenue"* service contract rates, BFSF payments from Manufacturer Defendants for their respective products increased 3-5 fold along with the severe price increases.

79. In addition, most of the Manufacturer Defendant products have faced moderating and/or eroding US prescription volume trends due to rising competition from new drug category entrants. In the inflammatory

specialty drug category, two new anti-TNF drugs have increased the competitive pressure on AbbVie's Humira and Amgen's Enbrel. In the MS category, the number of US drugs with similar efficacy profiles has doubled from four to eight just since 2009, placing severe competitive pressure on already mature or declining incumbent products. With moderating and or declining prescription trends, the incentive for and financial reliance on price inflation for growth for both Defendant parties has typically escalated each year since the start of Part D.

80. For one of the Manufacturer Defendants, Pfizer, the Relator has targeted numerous brand products for severe price-related fraud in this complaint. Pfizer faced severe US sales erosion in recent years due to a swath of major patent expirations. Over the past decade, Pfizer has lost patent protection on the majority of its prior major US revenue drivers, including Lipitor (cholesterol), Norvasc (cardiovascular), Zoloft (depression), Zyrtec (allergies), Detrol (incontinence), Geodon (schizophrenia) and Xalatan (glaucoma). Compounding the situation, most of Pfizer's remaining brand products have also faced eroding volume trends due to either clinical or competitive factors. Pfizer responded by preserving revenues for these remaining US brand drugs in moderating/declining use via massive anti-competitive, fraudulent price increases.

81. The anti-inflammatory category , including Defendant AbbVie's Humira and Defendant Amgen's Enbrel, is the second largest specialty drug spending category in Medicare Part D, after the multiple sclerosis category. Defendant AbbVie's Humira is the largest-selling drug both worldwide and in the US, with reported US sales of $1.2 billion in 2006, rising to $6.5 billion in 2014. Defendant Amgen's Enbrel is among the top-five selling drugs in the US, with reported US sales of $2.5 billion in 2005, rising to $4.4 billion in 2014. Two additional, clinically-similar anti-TNF drugs, Defendant UCB's Cimzia (estimated US 2014 reported sales of $667 million) and Defendant JNJ's Simponi (US 2014 reported sales of $544 million), were launched in the US in 2008 and 2009, respectively.

82. Indicative of severe anticompetitive activity, the price increases for all four anti-TNF drugs has accelerated in recent years. Based upon average product dosing, the AWP-based cost per patient/year price for all four

drugs has more than doubled from the $23-25,000 range in 2010 to $45-50,000 range in mid-2015, while category prescription growth has only averaged 6% over the past four years. See **Exhibit 6**. **Exhibit 6** and all subsequent Exhibits are in an Appendix at the end of the complaint. Based upon corporate-reported US sales, the Relator estimates that the average Manufacturer Defendant reported annual revenues per treated anti-TNF patient have increased by 121% from $17,453 in 2005 to $38,540 in 2014. See **Exhibit 7**.

83. Combined Manufacturer Defendant-reported US sales for these four anti-TNF drugs has more than quadrupled from $3.0 billion in 2005 to $12.1 billion in 2014, with two-thirds of this growth driven by severe price increases. Without price increases since the start of Part D, AbbVie's 2014 US Humira sales would have been approximately $3.0 billion or 46% of actual reported sales. In the case of Amgen's Enbrel, price increases have driven virtually all the product's sales growth since the start of Part D, despite an estimate 1% decline in the number of treated US patients between 2005 and 2014. Without price increases since the start of Part D, Amgen's 2014 US Enbrel sales would have been approximately $2.5 billion, $1.9 billion or 44% less than actual reported sales. Given the potential for severe competition among these similar agents in a properly-functioning competitive market, the Relator concluded that all of this category price inflation was enabled by BFSF-related fraud.

84. Based upon physician specialist discussions, the Relator estimates that Medicare Part D accounts for 30% of the US ant-TNF drug prescriptions. Using the estimated *"4% of revenue"* service contract rate, the Relator estimates that $259 million of fraudulent Part D BFSFs have been paid by the Manufacturer Defendants (AbbVie, Amgen, UCB and Johnson & Johnson) to the PBM Defendants in anti-TNF drug category between 2006 and 2014, with the fraud ongoing. Assuming a flat *"4%"* BFSF contract rate, the Relator estimates that average BFSF payment per patient per year to the PBM Defendants for the anti-TNF drugs has doubled from $703 in 2005 to $1,419 in 2014. See **Exhibit 7**.

85. The Relator estimates far larger cumulative fraudulent Part D anti-TNF drug sales of $6.5 billion enabled by the BFSF fraud between 2006 and 2014, with the fraud ongoing. Due to the cumulative impact of severe

price increases, the annual Part D sales fraud estimate for the four drugs has increased from $101 million in 2006 to $1.8 billion in 2014, with the pace accelerating in recent years. Due to their dominant combined prescription market share (100% in 2005, 92% in 2014), most of the fraudulent sales are attributed to Humira and Enbrel. The Relator estimates cumulative 2006-2014 Part D fraudulent sales for Humira, Enbrel, Cimzia and Simponi of $3.4 billion, $2.7 billion, $171 million and $194 million, respectively, through 2014, with the fraud ongoing and accelerating. See **Exhibit 8**.

86. In Medicare, injectable cancer agents are primarily reimbursed via Medicare Part B, while oral agents are reimbursed via Part D. As such, the oral CML category, including Defendant Novartis' Gleevec and Tasigna, as well as Defendant Bristol Myers Squibb's Sprycel, is the largest cancer spending category in Medicare Part D. All three of these CML drugs are routinely prescribed by physicians for the first-line treatment of CML. Defendant Novartis' Gleevec, with US sales of $524 million in 2005, rising to $2.2 billion in 2014, is the second highest spending cancer drug in Medicare Part D, after Celgene's multiple myeloma therapy, Revlimid. Defendant Novartis' second entrant in the CML category, Tasigna (US launch 2007) generated US sales of $540 million in 2014. Defendant Bristol Myers Squibb reported US sales of $671 million in 2014 for its CML drug, Sprycel (US launch 2006). Combined Manufacturer Defendant-reported US sales for these three CML therapies has increased from $524 million in 2005 to $3.4 billion in 2014, with 85% of this growth driven by severe price increases.

87. Indicative of worsening anticompetitive pricing activity, the price increases for all three first-line CML drugs have further accelerated in recent years, reaching uniform severe price levels in 2015. Based upon standard patient dosing, the AWP-based annual cost per patient for Novartis' Gleevec has increased from $48,050 in 2008 to $147,788 in mid-2015. The AWP-based annual cost per patient for Bristol Myers Squibb's Sprycel has increased from $80,005 in 2008 to $151,211 in mid-2015. The AWP-based annual cost per patient for Novartis' Tasigna has increased from $91,395 in 2008 to $151,269 in mid-2015. See **Exhibit 9**.

88. The vast price inflation of market-leading Gleevec has been the major driver of fraud in the CML category.

Based upon reported US sales, the Relator estimates that the average annual Novartis reported US revenues per Gleevec-treated patient have increased 246% from $29,659 in 2005 to $102,543 in 2014. See **Exhibit 10**. This 3.5-fold increase in revenues per patient has occurred despite only an estimated 20% increase in US Gleevec-treated patients between 2005 and 2014. The indication of Gleevec fraud has been even more severe in recent years. Novartis' reported revenues per US Gleevec-treated patient increased by approximately $40,000 between 2010 and 2014, with only a 2% increases in annual prescriptions. See **Exhibit 11**. Without price increases since the start of Part D, Novartis' 2014 US Gleevec sales would have been approximately $628 million in 2014, $1.5 billion or 71% less than actual reported sales. Given the potential for severe competition among these three first-line CML therapies, in a properly-functioning competitive market, the Relator concluded that all of this category price inflation was enabled by BFSF-related fraud.

89. Based upon physician specialist discussions, the Relator estimates that Medicare Part D accounts for 55% of the US oral CML drug prescriptions. Using the estimated *"4% of revenue"* service contract rate, the Relator conservatively estimates $167 million of fraudulent Part D BFSFs payments by the Manufacturer Defendants (Novartis and Bristol Myers Squibb) to the PBM Defendants in oral CM drug category between 2006 and 2014, with the fraud ongoing and accelerating. Assuming a stable *"4%"* BFSF contract rate, the Relator estimates that the average BFSF payment per patient per year to the PBM Defendants for these three first-line CML drugs has nearly quadrupled from $1,186 in 2005 to $4,240 in 2014. See **Exhibit 10**.

90. The Relator estimates far larger fraudulent Part D CML drug sales of $4.1 billion enabled by the BFSF fraud between 2006 and 2014, with the fraud ongoing. Due to the cumulative impact of severe price increases, the estimated annual Part D fraud in the CML category has increased from $25 million in 2006 to $1.1 billion in 2014. Due to its long availability, moderating volume and severe price inflation, Novartis' Gleevec accounts for the majority of Part D CML category fraud. The Relator estimates cumulative 2006-2014 Part D fraudulent sales of $3.5 billion, $198 million and $488 million for Gleevec, Tasigna and Sprycel, respectively, with the fraud ongoing and escalating. See **Exhibit 12**.

91. The Relator's investigation indicates that *"percent of revenue"* BFSF contracts appear particularly inappropriate for fast-inflating, extreme-priced oral specialty drugs, given the typically modest level of legitimate clinical support service needs relative to injectable drugs. Despite robust claims of clinical input by the PBM Defendants, Relator discussions with numerous CML physicians uniformly indicate a minimal role of the PBM Defendants in patient management beyond drug delivery and financial assistance.

92. The diabetes category represents the highest spending drug category in Medicare Part D. The US diabetes category is comprised of four distinct brand drug sub-segments. The major brand oral diabetes segments include dipeptidyl peptidase-4 (DPP-4) inhibitors and sodium co-transporter-2 (SGLT-2) inhibitors. The major brand injectable diabetes segments include insulins and glucacon-like peptide-1 (GLP-1) receptor agonists. Indicative of anti-competitive pricing behavior, despite escalating competition from an array of new product entrants, severe and virtually identical lockstep price inflation has occurred in all four of these major diabetes drug categories since the start of Part D. For instance, the average annual AWP-based cost/patient of oral DPP-4 drugs (only Merck's Januvia in 2006, but now four highly-similar molecules) has increased from $2,100 in 2005 to a nearly identical $4,800 for all agents in early 2015. *Truven Analytic/Redbook pricing database.*

93. For insulin drugs, the Relator compared annual patient cost trends assuming an average 50 unit daily dose for each product. According to clinical references, diabetics commonly require total daily insulin in the 100 units per day range, divided between long-acting and short-acting versions. However, the variability of insulin dosing among patients can vary widely depending upon factors such as weight, diet and insulin resistance/sensitivity. In the long-acting insulin segment, the AWP inflation for Sanofi's Lantus (FDA-approved 2000) and Novo Nordisk's Levemir (FDA-approved 2005) has been staggering. The average annual AWP-based cost/patient for both products has increased nearly four-fold between 2006 and 2014, from $1,400-1,500/patient to $5,442/patient. Indicative of accelerating anti-competitive behavior, the AWP cost for both Lantus and Levemir have increased by 68% and 58%, respectively, from the start of 2013 through early 2015. See **Exhibit 13**. Similarly, the average annual AWP-based cost/patient for the decades-

old, clinically identical, short-acting insulins, Eli Lilly's Humulin (FDA-approved 1982) and Novo Nordisk's Novolin (FDA-approved 1991), have increased more than four-fold in lockstep from the $606-630 range in 2005 to an identical $2,640 in early 2015. Indicative of accelerating anti-competitive behavior, the AWP cost for both Humulin and Novolin have also increased by an identical 58% from the start of 2013 through mid-2015. See **Exhibit 14**. The price inflation among long-marketed, clinically-interchangeable, short-acting insulin analogues, namely Eli Lilly's Humalog (FDA-approved 1996), Novo Nordisk's Novolog (FDA-approved 2000) and Sanofi's Apidra (FDA-approved 2004) has also been uniform and severe. The average annual AWP-based cost/patient for all three insulin analogs has increased three-fold from the $1,500 range in 2006 to the $4,000-4,500 range in 2014. Indicative of accelerating anti-competitive behavior, the AWP cost for Humalog, Novolog and Apidra have increased by 59%, 54% and 109%, respectively, from the start of 2013 through mid-2015. With ubiquitous severe brand drug price inflation, despite severe competition, BFSF fraud appears rampant across the US diabetes drug marketplace.

94. In this complaint, the Relator specifically targets three insulin therapies, Sanofi's Lantus, Sanofi's Apidra and Eli Lilly's Humulin, for which US price-related sales fraud appears most severe. Sanofi's long-acting insulin Lantus is, by far, the top-selling diabetes drug in the US market, with reported US sales of $717 million (based on Sanofi's reported average annual US/Euro exchange rate) in 2005, rising to $4.23 billion in 2014. Sanofi first reported separate US sales of Apidra of $54 million in 2009, rising to $131 million in 2014. Eli Lilly reported US Humulin sales of $368 million in 2005 and $713 million in 2014.

95. Combined Manufacturer Defendant-reported US sales for these three insulin therapies have increased more than five-fold from $1.3 billion 2005 to $6.7 billion in 2014, with 86% of this growth due to severe price increases. See **Exhibit 15**. Indicative of accelerating anti-competitive activity, in recent years the US manufacturer-reported sales trends for these three insulin products have vastly diverged from underlying patient utilization trends. For instance, Sanofi-reported US Lantus annual sales have more than doubled (+106%) from the $2.8 billion range in 2010 to the $5.8 billion range in 2014, despite only a 23% increase in annual US prescriptions over the time period. See **Exhibit 16**. Without price increases since the start of

Part D, Sanofi's US Lantus sales would have been approximately $2.1 billion in 2014, 63% less than actual reported US sales of $5.8 billion. Sanofi-reported US Apidra annual sales have increased more than 120% from the $82 million range in 2010 to the $181 million range in 2015, despite only a 49% increase in annual prescriptions over the time period. The disparate trends are even more severe for Eli Lilly's Humulin. Lilly-reported annual US Humulin sales have increased by 51%, from $471 million in 2010 to $713 million in 2015, despite a 28% decline in annual US prescriptions over the same timeframe. Without price increases since the start of Part D, Eli Lilly's 2014 US Humulin sales would have been approximately $213 million, $500 million or 70% less than actual reported sales. The Relator alleges that all the vast price inflation for these three insulin therapies has been enabled by BFSF-related fraud centered on Part D.

96. Based upon physician discussions, the Relator estimates that Medicare Part D accounts for 30% of the US prescriptions for these three insulin therapies. Using the estimated *"4% of revenue"* service contract rate, the Relator estimates cumulative fraudulent Part D BFSFs payments of $178 million from the Manufacturer Defendants (Sanofi and Eli Lilly) to the PBM Defendants in the US insulin market between 2006 and 2014, with the fraud ongoing and accelerating. Assuming a stable *"4%"* BFSF contract rate, the Relator estimates that the average BFSF payment per patient per year to the PBM Defendants for these three insulin therapies has more than tripled from $40 in 2005 to $134 in 2014. Due to the lower insulin pricing levels, the per-patient estimate of BFSF fraud with insulin therapies is far less than for extreme-priced anti-TNF and CML cancer specialty drugs. However, the overall magnitude of direct BFSF fraud with the insulin therapies is similar to the anti-TNF and CML categories due to the far larger size of the treated diabetes population. See **Exhibit 15**.

97. The Relator estimates far larger cumulative fraudulent Part D insulin drug sales for these three products of $4.4 billion between 2006 and 2014, with the fraud ongoing and accelerating. Due to the cumulative impact of severe price increases, the estimated annual Part D fraud for these three insulin products has increased from $24 million in 2006 to $1.3 billion in 2014, with the pace accelerating in recent years. Due to its large market share, Sanofi's Lantus accounts for the majority of the diabetic insulin category fraud. The Relator

estimates cumulative 2006-2014 Part D fraudulent sales of $3.8 billion, $43 million and $536 million for Lantus, Apidra and Humulin, respectively, with the fraud ongoing and accelerating. See **Exhibit 17**.

98. Manufacturer Defendant Pfizer has exhibited an astounding disparity in recent years between reported US sales for many of its largest brand drugs and their IMS prescription trends. The seven Pfizer brand products targeted in this complaint, namely Lyrica (for seizures and neurologic pain), Viagra (impotence), Celebrex (arthritis/pain), Chantix (smoking cessation), Premarin (menopausal symptoms/osteoporosis), Pristiq (depression) and Relpax (migraines), accounted for $7.4 billion or 39% of Pfizer's US sales of $19.1 billion in 2014. Overall, the Relator estimates that Pfizer has paid the PBM Defendants approximately $134 million in fraudulent Part D BFSF fees for these seven products between 2006 and 2014, with the fraud ongoing. See **Exhibit 18**. Overall, the Relator estimates that Pfizer has garnered fraudulent Part D sales of approximately $3.6 billion between 2006 and 2014, with the fraud ongoing. Due to the cumulative impact of severe price increases, the estimated annual Part D sales fraud for these seven Pfizer products has increased from $72 million in 2006 to $942 million in 2014, with the pace accelerating in recent years. See **Exhibit 19**.

99. Lyrica is Pfizer's largest-selling US product, with reported US sales rising from $717 million in 2006 to $2.32 million in 2014. Severe price increases have accounted for nearly 80% of Lyrica's US growth over this period. Just since 2010, Pfizer's realized price per patient for Lyrica has increased 57% with only 4% prescription growth. See **Exhibit 20**. Without price increases since the start of Part D, Pfizer's 2014 US Lyrica sales would have been approximately $1.1 billion or 53% less than actual reported sales. The Relator alleges that all of Lyrica's price driven growth since the start of Part D has been enabled by BFSF fraud.

100. The Relator estimates that Part D accounts for 30% of Lyrica's US prescriptions. Using the estimated *"4% of revenue"* service contract rate, the Relator estimates that $47 million of cumulative fraudulent Part D BFSF payments have been paid by the Manufacturer Defendant Pfizer to the PBM Defendants for Lyrical between 2008 and 2014, with the fraud ongoing and accelerating. See **Exhibit 18**. The Relator estimates far

larger fraudulent Part D Lyrica sales for Lyrica of $1.2 billion between 2008 and 2014, with the fraud ongoing and accelerating. Due to the cumulative impact of severe price increases, the estimated annual Part D sales fraud for Lyrica has increased from $47 million in 2008 to $365 million in 2014, with the pace accelerating in recent years. See **Exhibit 19**.

101. The diverging Pfizer-reported US revenue and patient usage trends has been even more stark for many other of Pfizer's other remaining major US brand drugs, namely Viagra (impotence), Celebrex (arthritis/pain), Chantix (smoking cessation), Premarin (menopausal symptoms/osteoporosis), Pristiq (depression) and Relpax (migraines). Between 2010 and 2014, Pfizer reported an increase in annual US sales of 15%, 10%, 14%, 5%, 37% and 29% for Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax, respectively, despite a marked deterioration in prescription volume for all these products, See **Exhibit 20**. According to IMS, the annual total prescriptions declined 21%, 20%, 29%, 41%, 22% and 18% for Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax, respectively, between 2010 and 2014. As such, the US sales for all of these brands would have declined significantly without massive price increases. Based upon corporate-reported sales and IMS trends, the average annual cost of therapy realized by Pfizer for these older brands between 2010 and 2014 increased by 45%, 38%, 61%, 78%, 75% and 57% for Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax, respectively. With all of these products facing severe competitive threats, the Relator alleges that all the price-driven revenue gains since the start of Part D have been enabled by BFSF fraud.

102. The Relator estimates that Part D accounts for 10%, 35%, 15%, 30%, 25%, and 15% of Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax US prescriptions, respectively. Using the estimated *"4% of revenue"* service contract rate, the Relator estimates that $13, $50, $3, $14, $6 and $1 million of cumulative fraudulent Part D BFSF payments have been paid by Pfizer to the PBM Defendants for Viagra, Celebrex, Chantix, Premarin, Pristiq and Relpax, respectively, between 2007 and 2014, with the fraud ongoing and accelerating. See **Exhibit 18.** The Relator estimates far larger cumulative fraudulent Part D Pfizer drug sales of $347 million, $1.4 billion, $77 million, $348 million, $160 and $32 million Viagra, Celebrex, Chantix, Premarin,

Pristiq and Relpax, respectively, between 2006 and 2014, with the fraud ongoing and accelerating. Due to the cumulative impact of severe price increases, the estimated combined annual Part D fraud for these six Pfizer brands has increased from $72 million in 2006 to $942 million in 2014, with the pace accelerating in recent years. See **Exhibit 19**.

103. Given the wide discrepancy between US manufacturer-reported sales and prescription trends, most of the financial benefit from BFSF-related pricing fraud in this case has accrued to the Manufacturer Defendants. However, due the severe magnitude of relentless price increases and their cumulative impact, the direct BFSF fraud paid to the PBM Defendants is also considerable.

104. The magnitude of direct BFSF fraud for each PBM Defendant will depend upon numerous individual company factors, including Part D product market shares, particular manufacturer service contract terms, partnership terms and the FMV assessment of services provided. Given PBM/specialty pharmacy industry complexity and lack of transparency, forensic evaluation of related subsidiary and partnership transactions/transfers will be essential.

105. Given the systemic nature of the scheme, the Relator would expect the greatest amount of BFSF fraud at the PBM Defendants with the largest share of Part D beneficiaries. In **Exhibit 21**, the Relator provides the combined PDP/Medicare Advantage enrollment at the end of 2012. Approximately 83% of Medicare Advantage enrollees receive the Part D benefit which is governed by the same laws/regulations as the standalone PDP plans. At the end of 2012, United HealthGroup had the largest share of the Part D program, with full PBM control of 6.4 million beneficiaries and a 20.5% market share. Express Scripts had full PBM control of 5.2 million or 17.0% of beneficiaries. Including its partnership with Anthem, Express had PBM influence on 6.6 million or 20.2% of beneficiaries. Humana had full PBM control of 4.8 million or 15.6% of beneficiaries. CVS Caremark had direct PBM control of 4 million beneficiaries. Including its partnership with Aetna, CVS Caremark had PBM influence on 4.9 million or 15.7% of beneficiaries. Overall, these four largest Part D operators had significant PBM influence on 72% of Part D beneficiaries at the end of 2012.

106. The magnitude of BFSF fraud among the PBM Defendants likely also correlates with respective market shares in the broader US PBM and specialty pharmacy industries. In many instances, the PBM Defendants likely negotiate service contracts with drug manufacturers across business lines, including private plans and Medicare Part D. As such, the Relator would expect the PBM Defendants with dominant overall industry market shares to obtain the highest service fee contract rates with Manufacturer Defendants, especially for many of the wide-distribution, long-marketed products targeted in this complaint.

107. As per **Exhibit 22**, PBM Defendants Express Scripts and CVS Caremark, together controlled 48% and 53% of the overall US PBM and specialty pharmacy industries, respectively, in 2013. With less negotiating leverage, smaller PBM Defendants likely receive lower service fee contract rates with the Manufacturer Defendants. However, the Relator alleges that all the PBM Defendants have benefited considerably from systemic BFSF fraud since service arrangements tied to vast price inflation have become ubiquitous in Medicare Part D.

108. The PBM/specialty pharmacy/drug distribution industries, as well as the Part D/Medicare Advantage programs, continue to consolidate at an astounding pace. In November 2014, Defendant CVS Caremark began providing mail order pharmacy services for Defendant Wellcare. On May 21, 2015, CVS Caremark announced the acquisition of Omnicare, which is a leading pharmacy manager for long term care facilities, which include significant Part D drug volume. On June 15, 2015, CVS Caremark announced the acquisition of Target's 1,660 retail pharmacies across 47 states. On July 6, 2015, Defendant Aetna announced plans to acquire Defendant Humana; the merger is expected to close in the second half of 2016. On July 23, 2015, Defendant UnitedHealth Group consummated is acquisition of Defendant Catamaran which was announced on March 31, 2015. On July 24, 2015, Defendant Anthem announced plans to acquire Defendant Cigna; the merger is expected to close in the second half of 2016.

109. With the acquisitions announced in recent months, the Relator estimates that the largest PBM Defendants (Express Scripts, CVS Caremark, UnitedHealth Group and Humana) will soon control nearly 80% of Part D

enrollment, likely further escalating already severe BFSF fraud in the program. The broader PBM and specialty pharmacy industries will similarly become more concentrated following recently completed and proposed acquisitions.

JURISDICTION AND VENUE

110. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. 3730(e), there has been no statutorily relevant public disclosure of the *"allegations or transactions"* in this Complaint. Relator is the original source of the facts and information alleged in this Complaint.

111. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C.§3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, the Defendants can be found in this District and /or transact business in this District.

112. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District. At all times relevant to this Complaint, Defendants regularly conducted substantial business within this District, maintained employees in this District, and/or made significant sales within this District. In addition, statutory violations, as alleged herein, occurred in this District.

PARTIES

113. Plaintiff/Relator John R. Borzilleri, MD *("Relator"*), an investment fund manager and physician, is a resident of Cutchogue, New York. The Relator has been a professional healthcare industry investment analyst

for twenty five years. The Relator has dedicated the past three years to an extensive effort to identify the factors behind the extreme price inflation in the US brand drug market, with a particular focus on fast-inflating, extreme-priced specialty drugs. The Relator is a licensed physician in the State of New York.

114. Defendant AbbVie, Inc. (*"AbbVie"*) is a Delaware corporation, with its U.S. headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. On January 1, 2013, AbbVie became an independent, publicly-traded company as a result of the distribution by Abbott Laboratories of 100 percent of the outstanding common stock of AbbVie to Abbott's shareholders. AbbVie focuses on anti-inflammatory conditions, infectious disease, and hormone replacement. AbbVie reported worldwide revenue $19.96 billion in 2014. Pertaining to this case, AbbVie markets Humira in the United States for the treatment of rheumatoid arthritis, psoriatic arthritis, psoriasis, Crohn's disease, ulcerative colitis and ankylosing spondylitis. In 2014, Humira accounted for 63% of AbbVie's global sales.

115. Defendant Amgen, Inc. *("Amgen"*) is a Delaware corporation, headquartered at One Amgen Center Drive, Thousand Oaks, California 91320-1799. Amgen discovers, develops, manufactures, and markets human therapeutics in the oncology, inflammatory, cardiovascular and renal disease categories. Amgen reported worldwide sales of $19.3 billion in 2014, with 76% of sales in the United States. Pertaining to this case, Amgen markets Enbrel in the United States for the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis and plaque psoriasis. Enbrel accounted for 24% of Amgen's global sales in 2014.

116. Defendant Bristol-Myers Squibb, Inc. *("Bristol Myers Squibb"*) is a Delaware corporation, headquartered at 345 Park Avenue, New York, NY 10154. Bristol-Myers Squibb primarily generates revenues in the oncology, virology, cardiovascular, neuroscience, immunology, fibrosis and genetic diseases therapeutic areas. Bristol-Myers Squibb reported worldwide sales of $15.93 billion in 2014, with 49% of sales in the United States. Pertaining to this case, Bristol-Myers Squibb markets Sprycel in the United States for the treatment of chronic myeloid leukemia. Sprycel accounted for 9% of Bristol-Myers Squibb's global revenues

in 2014.

117. Defendant Johnson & Johnson *("Johnson & Johnson"*) is a New Jersey corporation, headquartered at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is a diversified healthcare company with large pharmaceutical, consumer and medical device subsidiaries. In the pharmaceutical segment, Johnson & Johnson primarily generates revenues in the oncology, immunology, infectious disease, cardiovascular, neuroscience and metabolic therapeutic areas. Johnson & Johnson reported worldwide sales of $74.3 billion in 2014, with 47% of sales in the United States. Pertaining to this case, Johnson and Johnson markets Simponi in the United States for the treatment of rheumatoid arthritis, psoriatic arthritis, ulcerative colitis and ankylosing spondylitis. Simponi accounted for 4% of JNJ's global pharmaceutical revenues of $28.1 billion in 2014.

118. Defendant Eli Lilly and Company *("Eli Lilly"*) is an Indiana corporation, headquartered at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly is a leading healthcare company focused on human pharmaceuticals and animal health. In its human pharmaceutical division, Eli Lilly focuses on the diabetes, oncology, neuroscience and cardiovascular therapeutic areas. Eli Lilly reported worldwide sales of $19.6 billion in 2014, with 46% of sales in the United States. Pertaining to this case, Eli Lilly markets Humulin in the United States for the treatment of diabetes. Humulin accounted for 7% of Eli Lilly's global revenues in 2014.

119. Defendant Novartis AG *("Novartis"*) is a multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of healthcare products. Key Novartis subsidiaries in the United States include Novartis Corporation and Novartis Pharmaceuticals Corporation, both based in East Hanover, New Jersey. Novartis reported worldwide sales of $58.0 billion in 2014. Pertaining to this case, Novartis markets Gleevec and Tasigna in United States for the treatment of chronic myeloid leukemia. Gleeven and Tasigna together accounted for 11% of Novartis' global revenues in 2014.

120. Defendant Pfizer, Inc. *("Pfizer"*), a Delaware corporation, is headquartered in New York City at 235 East 42nd Street, New York, New York 10017. Pfizer is among the world's largest pharmaceutical companies

with a focus on cardiovascular/metabolic disease, immunology, inflammation and neuroscience. Pfizer reported worldwide revenues of $49.6 billion in 2014. Related to this case, Pfizer markets the following products (indications) in the United States: Lyrica (diabetic neuropathy, postherpetic neuralgia, seizures and fibromyalgia); Viagra (erectile dysfunction); Celebrex (osteoarthritis, pain); Chantix (smoking cessation); Premarin (hormone replacement and osteoporosis); Pristiq (depression); Relpax (migraines). In 2014, these products accounted for 25% of Pfizer's global sales.

121. Defendant Sanofi N.A. *("Sanofi")* is a global healthcare company headquartered in France at 54, Rue La Boétie, 75008 Paris, France. Sanofi's business segments include human pharmaceuticals, consumer products and animal health. Within its human pharmaceutical segment, Sanofi focuses on the diabetes, multiple sclerosis, oncology and rare disease segments. Sanofi reported worldwide sales of approximately $46.6 billion in 2014, at prevailing exchange rates. Pertaining to this case, Sanofi markets Lantus and Apidra in the United States for the treatment of diabetes. In 2014, Lantus accounted for approximately 19% of Sanofi's global sales. In 2014, Apidra accounted for approximately 1% of Sanofi's global sales.

122. Defendant UCB Group N.A. *("UCB")* is a Belgium-based global biopharmaceutical company headquartered at Alle de la Recherche 60, 1070 Brussels, Belgium. In human pharmaceuticals, UCB primarily focuses on the immunology and neurologic segments. UCB reported worldwide sales of approximately $4.4 billion in 2014, at prevailing exchange rates. Pertaining to this case, UCB markets Cimzia in the United States for the treatment of rheumatoid arthritis, Crohn's disease, psoriatic arthritis and ankylosing spondylitis. In 2014, Cimzia accounted for 27% of UCB's global sales.

123. Defendants AbbVie, Inc., Amgen, Inc., Bristol-Myers Squibb, Inc., Johnson & Johnson, Eli Lilly and Company, Novartis AG, Sanofi S.A. and UCB Group S.A. are collectively identified as the *"Manufacturer Defendants"* in this complaint.

124. Defendant Express Scripts Holding Company *("Express Scripts")*, headquartered in St. Louis, MO, and

its subsidiaries, is the largest PBM company in the United States, offering a full range of services to our clients, which include managed care organizations, health insurers, third-party administrators, employers, union-sponsored benefit plans, workers' compensation plans and government health programs. Through its licensed insurance subsidiaries (i.e., Express Scripts Insurance Company *("ESIC")*, Medco Containment Life Insurance Company and Medco Containment Insurance Company of New York), Express Scripts operates as Part D PDP sponsors offering PDP coverage and services to Part D beneficiaries. Express Scripts also, through our core PBM business, provides Part D-related products and services to other PDP sponsors, MA-PDPs and other employers and clients offering Part D benefits to Part D eligible beneficiaries. Accredo Health Group and CuraScript Specialty Pharmacy, are focused on dispensing infused, injectable, inhaled and oral drugs that require a higher level of clinical services and support compared to what typically is available from traditional pharmacies. Express Scripts reported revenues and net income of $100.9 billion and $2.0 billion, respectively, in 2014.

125. Defendant CVS Caremark Corporation *("CVS Caremark")*, headquartered in Woonsocket, RI, and its subsidiaries, is the largest integrated pharmacy health care provider in the United States. The Pharmacy Services Segment provides a full range of PBM services to our clients consisting primarily of employers, insurance companies, unions, government employee groups, managed care organizations ("MCOs") and other sponsors of health benefit plans and individuals throughout the United States. In addition, through its SilverScript Insurance Company ("SilverScript") subsidiary, CVS Caremark is a national provider of drug benefits to eligible beneficiaries under the Federal Government's Medicare Part D program. The Pharmacy Services Segment operates under the CVS Caremark® Pharmacy Services, Caremark®, CVS Caremark®, CarePlus CVS/pharmacy®, RxAmerica®, Accordant®, SilverScript® and Novologix® names. CVS Caremark reported revenues and net income of $139.4 billion and $4.64 billion, respectively, in 2014.

126. Defendant UnitedHealth Group, Inc., *("UnitedHealthcare")* headquartered in Minnetonka, MN, and its subsidiaries, is a diversified health and well-being company. UnitedHealth Group completed the acquisition of Catamaran Corporation in July 30, 2015. UnitedHealthcare provides health care benefits to a full spectrum

of customers and markets. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits for Medicare beneficiaries and retirees. UnitedHealthcare Community & State manages health care benefit programs on behalf of state Medicaid and community programs and their participants. Optum is a health services business serving the broad health care marketplace, including payers, care providers, employers, government, life sciences companies and consumers, through its OptumHealth, OptumInsight and OptumRx businesses. UnitedHealthcare Medicare & Retirement provides Medicare Part D benefits to beneficiaries throughout the United States and its territories through its Medicare Advantage and stand-alone Medicare Part D plans. UnitedHealthcare Medicare & Retirement offers two standalone Medicare Part D plans: the AARP Medicare Rx Preferred and the AARP Medicare Rx Saver plans. UnitedHealth Group, Inc. reported revenues and net income of $130.5 billion and $5.62 billion, respectively, in 2014.

127. Defendant Humana, Inc. *("Humana")*, headquartered in Louisville, KY, and its subsidiaries, is a leading health care company that offers a wide range of insurance products and health and wellness services. During 2013, 75% of Humana's total premiums and services revenue were derived from contracts with the federal government. At December 31, 2013, Humana provided health insurance coverage under CMS contracts to approximately 2,068,700 individual Medicare Advantage members. Humana offers stand-alone prescription drug plans, or PDPs, under Medicare Part D, including a PDP plan co-branded with Wal-Mart Stores, Inc., or the Humana-Walmart plan. On July 6, 2015, Defendant Aetna announced its intention to acquire Humana; the transaction is expected to close in the second half of calendar 2016. Humana, Inc. reported revenues and net income of $48.5 billion and $1.15 billion, respectively, in 2014.

128. Defendant ANTHEM (formerly Wellpoint, Inc.; name changed on December 3, 2014) *("Anthem")*, and its subsidiaries, is one of the largest health benefits companies in the United States. Anthem is an independent licensee of the Blue Cross and Blue Shield Association, or BCBSA, an association of independent health benefit plans. Anthem serves its members as the Blue Cross licensee for California and as the Blue Cross and Blue Shield, or BCBS, licensee for: Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia and Wisconsin. Anthem offers a wide variety

of senior plans, products and options such as Medicare supplement plans, Medicare Advantage and Medicare Part D Prescription Drug Plans, or Medicare Part D. Since December 1, 2009, Anthem has delegated certain functions and administrative services related to our integrated prescription drug products to Express Scripts under a ten year contract, excluding Amerigroup and certain self-insured members. Anthem reported revenues and net income of $73.0 billion and $2.57 billion, respectively, in 2014.

129. Defendant Cigna Corporation *("Cigna")*, headquartered in Bloomfield, CT, and its subsidiaries, is a global health services provider of medical, dental, disability, life and accident insurance and related products and services. Cigna's Medicare Part D prescription drug program provides a number of plan options, as well as service and information support to Medicare and Medicaid eligible customers. Cigna's plans are available in all 50 states and the District of Columbia. With a network of over 65,000 contracted pharmacies, Cigna Pharmacy Management is a comprehensive pharmacy benefits manager ("PBM") offering clinical integration programs and specialty pharmacy solutions. Under a 2013 agreement, Catamaran Corporation provides Cigna with access to their technology and service platforms, prescription drug procurement and inventory management capabilities, retail network contracting and claims processing services. Cigna reported revenues and net income of $34.9 billion and $2.1 billion, respectively, in 2014.

130. Defendant Aetna, Inc. *("Aetna")*, headquartered in Hartford, CT, and its subsidiaries, is one of the nation's leading diversified health care benefits companies. On May 7, 2013 (the “Effective Date”), Aetna acquired Coventry in a transaction valued at approximately $8.7 billion. Through annual contracts with CMS, Aetna offers HMO and PPO products for eligible individuals in certain geographic areas through the Medicare Advantage program. Aetna is also a national provider of the Medicare Part D Prescription Drug Program (“PDP”) in all 50 states and Washington, D.C. to both individuals and employer groups. Aetna offers pharmacy benefit management services and specialty and mail order pharmacy services to its members. Aetna's pharmacy fulfillment services are delivered by Aetna Specialty Pharmacy (“ASP”) and Aetna Rx Home Delivery®. ASP compounds and dispenses specialty medications and offers certain support services associated with specialty medications. In 2011, CVS Caremark began to perform the administration of

selected functions for Aetna's retail pharmacy network contracting and claims administration; mail order and specialty pharmacy order fulfillment and inventory purchasing and management; and certain administrative services for Aetna. On July 6, 2015, Aetna announced its intention to acquire Defendant Humana; the transaction is expected to close in the second half of calendar 2016. Aetna, Inc. reported revenues and net income of $58.0 billion and $2.0 billion, respectively, in 2014.

131. Defendant Wellcare Health Plans, Inc. *("Wellcare")*, headquartered in Tampa, FL, is a leading managed care company for government-sponsored health care coverage with a focus on Medicaid and Medicare programs. As of December 31, 2013, Wellcare offered MA plans in a total of 204 counties across 14 states, with over 15 million eligible beneficiaries in these service areas. Wellcare has contracted with CMS to serve as a plan sponsor offering stand-alone Medicare Part D PDP plans to Medicare-eligible beneficiaries through our PDP segment. Wellcare's PDP plans offer national in-network prescription drug coverage with more than 60,000 pharmacies, including a preferred pharmacy network, subject to limitations in certain circumstances. Wellcare offers PDP plans in 49 states and the District of Columbia. In November 2014, CVS Caremark began providing PBM services to Wellcare under a partnership agreement. Wellcare Health Plans, Inc. reported revenues and net income of $13.0 billion and $64 million, respectively, in 2014.

132. Defendants Express Scripts Holding Company, CVS Caremark Corporation, UnitedHealth Group, Inc., Humana, Inc., Wellpoint, Inc., Cigna Corporation, Aetna, Inc. and Wellcare Health Plans, Inc. are collectively identified as the *"PBM Defendants"* in this complaint.

THE LAW

The False Claims Act

133. The FCA provides in pertinent part, that:

a) Any person who (I) knowingly presents, or causes to be presented, to an officer or employee of the

United States Government or a memberof the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulentclaim paid or approved by the Government is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person.

b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (I) has actualknowledge of the information; (2) acts in deliberate ignorance of thetruth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

c) 31 U.S.C. §3729.

d) Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996,28 U.S.C. §2461 (notes), and64 Fed. Reg. 47099, 47103 (1999), the civil penalties were adjusted from $5,500 to $11,000 for violations occurring on or after September 29, 1999.

The Federal Anti-Kickback Statute

134. Congress first enacted the federal anti-kickback statute, 42 U.S.C. § 1320a-7b(b), in 1972 to protect the integrity of the Medicare and Medicaid programs. Congress strengthened the statute in 1977, and again in 1987, to ensure that kickbacks masquerading as legitimate transactions would not evade its reach. *See* Social Security Amendments of 1972, Pub. **L.** No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Anti-fraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

135. The anti-kickback statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for federally funded medical items, including items provided under Medicare and Medicaid. In pertinent part, the statute provides:

a) Illegal remuneration:

b) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind:

c) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

d) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

e) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

f) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or:

g) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good,

facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

h) 42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs and, effective August 6, 1997, civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

THE MEDICARE PROGRAM

136. Medicare is a federally funded and administered health insurance program for certain groups, primarily elderly and disabled persons. The Department of Health and Human Services ("HHS") administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). There are four major components to the Medicare program:

a) Part A, the hospital insurance benefits program.

b) Part B, the supplemental medical insurance benefits program, which generally pays for a percentage of certain medical and other health services, including physician services.

c) Part C, the Medicare Advantage program, which allows CMS to contract with public and private entities to provide, at a minimum, Medicare Part A and B benefits to certain Medicare beneficiaries.

d) Part D, the voluntary prescription drug benefit program.42 U.S.C. § 1395w-101, et seq.

137. Part D was established in 2003 by the Medicare Prescription Drug, Improvement, and Modernization Act, which set up a voluntary prescription benefits program for Medicare enrollees. Part D became effective January 1, 2006. Unlike Parts A and B, Medicare Part D is based on a private market model, wherein Medicare contracts with private entities, known as Part D *"sponsors"* to administer prescription drug plans. Part D benefits are provided by a Part D plan sponsor, which is either a prescription drug plan ("PDP"), a Medicare Advantage organization plan ("MA-PD plan), or a Program of All-Inclusive Care for the Elderly ("PACE").

138. A Part D sponsor submits a bid in the year prior to the calendar year in which Part D benefits will actually be delivered. The bid contains a per member per month ("PMPM") cost estimate for providing Part D benefits to an average Medicare beneficiary in a particular geographic area. From the bids, CMS calculates nationwide and regional benchmarks which represent the average PMPM cost. If the Part D plan sponsor's bid exceeds the benchmark, the enrolled beneficiary must pay the difference as part of a monthly premium.

139. When a pharmacy dispenses drugs to a Medicare beneficiary, it submits an electronic claim to the beneficiary's Part D plan and receives reimbursement from the plan sponsor for the costs not paid by the beneficiary. The Part D plan sponsor then notifies CMS that a drug has been purchased and dispensed through a document called a Prescription Drug Event ("PDE") record, which includes the amount paid to the pharmacy.

140. As a condition for receiving its monthly payment from CMS, a Part D Plan sponsor must certify the accuracy, completeness and truthfulness of all data related to the payment, which may include enrollment information, claims data, bid submission data, and any other data specified by CMS. 42 C.F.R. § 423.505(k)(1). If the claims data has been generated by a subcontractor of a Part D plan sponsor, such as a PBM, that entity must *"similarly certify"* that the claims data it has generated is accurate, complete and truthful, and must acknowledge that it will be used to obtain federal reimbursement. 42 C.F.R. § 452.505(k)(3).

141. Part D Plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(1). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs, contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

142. Part D Plan sponsors subcontract with many entities to provide drugs to the Medicare Part D beneficiaries enrolled in their plans, including subcontracts with PBMs and specialty pharmacies. PBMs can provide a variety of services to sponsors to help manage their prescription drug benefit. These services include processing prescription drug claims, contracting with pharmacies, managing formularies, as well as negotiating rebates with drug manufacturers. PBMs can be compensated for these services in a variety of ways, including receiving a fixed payment per claim or retaining a percentage of sponsors' rebates.

143. PBMs can also be directly compensated by drug manufacturers via designated *"bona fide service fees"* (BFSFs) for a wide array of product-related *"services"*, such as inventory management, patient education, phone support, shipping, reimbursement assistance, data reports, etc., which would have otherwise been performed by the manufacturer. BFSFs are excluded from government *"negotiated price"* calculations.

THE MEDICARE PART D BID AND SUBSIDY PROCESS

144. CMS has established a unique bid and reimbursement process in the administration of Part D with plan sponsors. Under Medicare Part D, plan sponsors are required to submit bids to CMS in the first week of June for the following calendar plan year. The bids are based upon the sponsor's estimate of its anticipated monthly drug costs for Part D beneficiaries in the plan, as well as administrative costs and expected profit. *OIG Report, Medicare Part D Reconciliation Payments for 2006 and 2007, OEI-02-08-00460, September 2009*. CMS uses the submitted data to determine individual plan premium rates and monthly subsidy payments made to

plan sponsors for the following calendar plan year. The monthly subsidy payment schedule of Part D is designed to help plans effectively manage *"cash flow"* during a plan year as actual drug costs accrue.

145. The plan sponsor bid cost estimates and related monthly subsidy payments consist of four distinct tranches. First, the sponsor must provide a cost estimate for the *"basic"* Part D benefit for a beneficiary of *"average"* health in the plan, for which it receives monthly *"Regular Subsidy"* payments. According to CMS, the *"Regular Subsidy"* monthly payments for Part D plans across the US are relatively similar since the amounts are based upon national beneficiary cost averages, with modest adjustments for age and health status in each particular plan.

146. Second, the plan sponsor must provide an estimate of the benefit cost for low-income (LIS) beneficiaries (approximately 30% of overall Part D enrollment) in the plan for the following calendar year, for which CMS provides monthly *"Low-Income (LIS) Subsidy*" payments. LIS beneficiaries are low-income elderly and disabled people, who commonly are afflicted with severe chronic medical conditions that often necessitate treatment with high-priced specialty drugs. Other than small copayments, CMS covers virtually all drug costs for LIS beneficiaries in Medicare Part D.

147. Third, the sponsor must estimate the cost of providing *"catastrophic"* drug coverage for non-LIS beneficiaries (70% of Part D enrollment) whose annual out-of-pocket spending exceeds the annual maximum threshold ($3,600 in 2006, rising to $4,750 in 2013). For *"catastrophic"* drug costs, CMS covers 80% of the estimated costs via monthly *"Reinsurance Subsidy"* payments; with plan sponsors and non-LIS beneficiaries responsible for 15% and 5% of spending over the threshold, respectively. In Part D, the use of high-priced specialty drugs is the primary driver of crossing the annual Catastrophic spending threshold. In contrast to *"Regular Subsidy"* payments, monthly *"LIS Subsidy"* and *"Reinsurance Subsidy"* payments among plans can vary widely, depending upon the enrollment and health status characteristics of a particular plan.

148. Finally, starting in 2011, CMS added the *"Gap Discount Subsidy"* as part of the ACA legislation, which requires drug manufacturers to provide price discounts to all Part D beneficiaries in the so-called *"donut hole"* coverage window. In plan bid submissions, plan sponsors must estimate the amount of manufacturer *"donut hole"* discounts for the following calendar year, for which CMS provides monthly *"Gap Discount Subsidy"* payments. Since CMS hired a Third Party Administrator (TPA), Palmetto GBA, to administer the Gap Discount program, the *"Gap Discount Subsidy"* payments appear to be *"pass through"* amounts from manufacturers to plans sponsors.

149. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit a *"Prescription Drug Event"* (PDE) record for each prescription for all covered drugs dispensed to enrollees. The PDE includes more than 50 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE does not provide drug costs paid by PBMs to drug manufacturers.

150. In addition, sponsors must submit quarterly and year-end DIR *("Direct and Indirect Remuneration")* reports to CMS to disclose any rebates or price concessions, which almost entirely come from manufacturers via PBM negotiations for the vast majority of plans.

151. Of note, both the PDE and DIR data are *"self-reported"*, with apparently limited CMS oversight or verification. *Medicare Part D - Prescription Drug Event Reconciliation Process, A-18-08-30102, June 1, 2010.* For the vast majority of Part D plans, the PDE and DIR reports are prepared by contracted PBMs, with limited controls by either CMS or unaffiliated plan sponsors.

152. Both *"Low-Income Subsidy"* and *"Reinsurance Subsidy"* plan sponsor payments undergo a reconciliation process after each plan year. In the case of *"Low-Income Subsidy"* payments, CMS guarantees full reimbursement of any cost over-runs, with no risk borne by plans sponsors, PBM subcontractors or drug manufacturers. In reconciliation, the cost-sharing responsibilities for excess non-LIS *"Catastrophic"* drug

spending are the same as during the bid process. Namely, CMS covers 80% of unlimited excess costs, with the plan sponsor and beneficiary responsible for 15% and 5%, respectively. CMS and plan sponsors share risk regarding for *"Catastrophic"* spending significantly above or below plan sponsor bid forecasts for a given year.

STATES RELEVANCE TO THE PART D FRAUD

153. As part of the 2003 MMA legislation, the drug benefit for many of the highest cost, most-severely ill beneficiaries *"dual eligibles"* beneficiaries were transferred, without recourse, from state Medicaid programs to Medicare Part D. *"Dual eligibles"* are low-income elderly and disabled beneficiaries eligible for both Medicaid and Medicare benefits. Former State *"dual eligibles"* account for the majority (63-70% each program year thus far) of Part D LIS beneficiaries which, in turn, have historically accounted for the majority (up to 70% in early program years) of Part D premium-priced specialty drug spending.

154. By law, each State is required to fund a significant portion of Medicare Part D spending for their respective *"dual eligible"* beneficiaries via *"phased-down contribution"* or *"clawback"* payments to CMS paid on a monthly basis. In the program years 2006 through 2014, State *"clawback"* payments accounted for 32-37% of Part D LIS Subsidy costs each year. Furthermore, the State Part D financial responsibilities are legally tied to Federal Medicaid matching transfers. As such, if any State fails or refuses to pay its CMS-determined *"clawback"* payments, the same amount will be deducted from its scheduled Federal Medicaid matching funds.

155. Prior to Medicare Part D, State *"dual eligible"* beneficiaries received their outpatient drug benefit via State Medicaid programs. Medicaid requires additional manufacturer rebates for brand price increases greater than inflation (CPI-Urban), whereas Medicare Part D provides no such protection. As such the State *"dual eligible"* drug costs and associated *"clawback"* payments have escalated along with the fraudulent price inflation in Medicare Part D. Overall, States made cumulative *"clawback"* payments to CMS of $61.8 billion

for the years 2006 through 2014.

PART D - VAST PRICE INFLATION; PBM COMPENSATION DRIVEN BY BFSFs, NOT REBATES

156. When the Medicare Part D program began, both legislators and CMS expected private competition to generate significant cost savings for seniors and to hold down drugs prices. In October 2003, as Congress was debating the Medicare Part D legislation, President George W. Bush claimed: *"The best way to provide seniors with modern medicine, including prescription drugs coverage...is to give them better choices under Medicare. If seniors have choices, health plans will compete for their business by offering better coverage at more affordable prices." The White House, President Calls on Congress to Complete Work on Medicare Bill (Oct. 29, 2003).*

157. In November 2003, Secretary of Health and Human Services, Tommy Thompson, stated: *"Health insurance companies are going to get into this market...The pharmaceutical benefit managers (PBMs) who will be taking over purchasing of the drugs are going to be able to purchase in bulk with the pharmaceutical companies and hold down prices." The Big Story with John Gibson, Fox News Network (Nov. 26, 2003).*

158. Key government officials actually suggested Medicare Part D drug cost savings would be even greater than in other federal drug programs, such as Medicaid. While awaiting implementation of the program, in September 2004, Medicare Administrator Mark McClellan claimed that the private insurers would be able to obtain *"the best"* prices for seniors. He stated: *"Our approach is expected to provide the best discounts on drugs, discounts as good or better than could be achieved through direct government negotiation." Testimony of Dr. Mark McClellan, Senate Finance Committee, Hearing on The Medicare Prescription Drug Benefit, 109th Cong. (Sept. 14, 2005).*

159. Legislative proponents and CMS clearly expected significant *"negotiated"* rebates/price concessions from drug manufacturers to be the primary method to limit elderly drug costs, to prevent severe brand drug

price inflation and to compensate PBMs and other service vendors for their efforts in the Medicare Part D program.

160. The Relator has found no evidence of legislative debate regarding the role of *"Bona Fide Service Fees"* (BFSFs) in Medicare Part D, with the issue remaining largely out of the public eye even more than nine years since the program's inception.

161. Considerable brand drug inflation in Medicare Part D commenced as soon as the program was implemented in January 2006. According to CMS's own data reported in comments to a January 2010 General Accounting Office (GAO) report (*GAO-10-242*): *"An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand name drugs (both specialty and non-specialty tier) between January 2006 and October 2009."* The price increases for many top-selling brand traditional and specialty drugs have been far more severe compared to this broad index both before and after October 2009.

162. In addition, counter to the CMS expectations, the percentage rate of rebates in Medicare Part D have been very modest compared to other federal programs. With a modest Part D manufacturer rebate rate since the start of the program, the profitability of the majority of brand drugs for manufacturers (and for service vendors receiving a percent of these rising drug costs) has greatly escalated in Medicare Part D. Of note, as per the 2015 annual report, the Medicare Trustees forecast a slight increase in manufacturer rebate rates to an average of 16.7% of annual Part D spending by the year 2022. This most recent rebate long-term rebate rate forecast is up from the 10% range from the Trustees 2013 annual report.

163. In sharp contrast, government rebates in the Medicaid program have been far larger, averaging 34% of program spending for the years 2006 through 2009. *OIE-03-10-00320, Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, August 2011*. The far larger rebate proportion in Medicaid is because its statutes, in sharp contrast to Medicare Part D, require that manufacturers provide additional rebates to CMS for any revenues generated by brand drug price increases greater than

general inflation (CPI-U, Consumer Price Index-Urban). Driven entirely by ongoing severe Part D price inflation, OIG's most recent comparison of Medicaid and Medicare Part D indicated further divergence in rebate trends. For the year, 2012, rebates for the top-spending 200 brand drugs in Medicare D were 15% of the program's spending versus 47% for Medicaid. *OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.*

164. In March 2011, the Office of Inspector General (OIG) of the Department of Health and Human Services released a report entitled *"Concerns with Rebates in the Medicare Part D Program". OIG HHS Report, OEI-02-08-00050, March 2011* The OIG analysis was based on all Part D sponsor rebate reports and plan bid data for 2008, as well as an in depth review of six selected sponsors. Consistent with the above discussion, the OIG disclosed that Medicare Part D sponsors reported receiving $6.5 billion in drug manufacturer rebates in 2008, corresponding to approximately 10% of total gross Part D drugs costs of $63 billion for the year.

165. However, central to these fraud allegations and contrary to legislative expectations, **PBMs *"RETAINED"* LESS THAN 1% OR ONLY $24 MILLION OF THE $6.5 BILLION** in total rebates reported to CMS in plan sponsor *"Direct and Indirect Remuneration"* (DIR) reports for 2008. In addition, 61% of plan sponsors reported that PBMs retained no Part D rebates in 2008. Of note, while other types of price concessions (such as discounts from pharmacies for prompt pay and legal settlements) are included in the DIR reports, manufacturer rebates accounted for 98% of all price concessions received by plan sponsors in 2008, according to the OIG report. As such, counter to legislative expectations, PBMs received minimal rebate compensation from drug manufacturers in 2008. Of note, this OIG report is the only federal document the Relator has been able to locate which discusses manufacturer rebates *"retained"* by PBMs in the Part D program.

166. As stated in the Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: *"CMS considers all remunerations received directly or indirectly from pharmaceutical*

manufacturers, with the exception of bona fide service fees, to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor." As such, since BFSFs were, by law, the only significant payments excluded from Part D sponsor DIR reports in 2008, virtually all PBM compensation for that year beyond the minimal reported retained rebates came in the form of BFSFs from manufacturers. Starting with the 2009 Part D plan year, CMS began increasing BFSF reporting requirements for plan sponsors. With the certification requirements for both plan sponsor and FDRs in Part D, these reporting requirements should encompass all BFSFs received by the PBM Defendants, including those paid to their PBM and specialty pharmacy entities. Failure to report BFSFs in excess of FMV has resulted in violations of both the FCA and the Anti-Kickback Statute.

167. Additional direct CMS data confirms both extreme price increases and very low level of rebates for many high-cost specialty drugs in Part D. In January 2010, the General Accounting Office (GAO) released a report (*GAO-10-242*), entitled: *Medicare Part D – Spending, Beneficiary Cost Sharing, and Cost Containment Efforts for High-Cost Drugs Eligible for Specialty Tier"*. The report, commissioned by Chairman Pete Stark of the Ways and Means Committee of the House of Representatives, appears to be the only specific, publicly-available, federal analysis of specialty drugs in Medicare Part D since the start of the program. The study analyzed specialty drug pricing and manufacturer price concession trends in the first three years of Part D, 2006 through 2008.

168. In the analysis, the GAO obtained specialty drug pricing and price concession data for 20 key specialty drugs from 7 large plan sponsors, which represented 51% of all Medicare Advantage Part D enrollment and 67% of standalone Part D enrollment in 2008. In the report, the GAO identified ten chronic conditions commonly treated with specialty drugs; then selected two therapies for evaluation from each therapeutic category.

169. For all reviewed specialty drugs, the GAO found the level of discounts/rebates was below the 9-11% average in the Medicare Part D program throughout the 2006-2008 period. In addition, the Medicare Part D

costs per patient had risen considerably for some major specialty drugs due to severe price inflation.

170. In the multiple sclerosis category, negotiated discounts for Biogen's Avonex were only 1.1-2.6% of list price, despite a 35% price increase over the two years. See **Exhibit 23.** Discounts for Teva's MS therapy were modestly higher, at 6.2-8.0% of list price during the period, with a 26% increase in cost of therapy over the two years. In the anti-TNF category, negotiated discounts for AbbVie's Humira were in the 6.1-8.2% of list price range, with 9% price inflation over the two years. For Amgen's Enbrel, negotiated discounts were lower, at 2.0-3.7% of list price, with 7% price inflation between 2006 and 2008. In the cancer space, no negotiated discounts were provided in any year for Novartis' Gleevec and Roche's Tarceva (an oral drug for lung cancer), despite 24% and 13% price escalation, respectively, between 2006 and 2008.

171. This GAO analysis confirms both the typically low and stable level of negotiated discounts for specialty drugs in Part D, even for product's exhibiting severe price inflation. As such, the vast majority of financial gains from specialty drug price inflation in Part D accrued to drug manufacturers (and PBMs via service fee contract arrangements) in the years 2006 through 2008.

172. The magnitude of price increases for the above noted specialty drugs and many other brand products has greatly accelerated since this dated GAO study. For instance, as per this GAO analysis, the average Part D cost per patient for AbbVie's Humira and Amgen's Enbrel was approximately $17,600 in 2008; the Part D cost per patient for both these therapies now approaches $50,000. Similarly, the average Part D cost patient for Novartis' Gleevec was about $40,700 in 2008; the average cost is now in the $140,000-150,000 range. In the multiple sclerosis category, the Part D cost per patient for Biogen's Avonex and Teva's Copaxone were $21-23,000 in 2008; the Part D cost per patients for these drugs now likely fall in the $65-70,000 range. With likely similar modest rebate rates for specialty drugs in Part D in more recent years, the vast majority of the enormous financial gains from massive price increases have been garnered by drug manufacturers and their collusive PBM partners.

173. All seven plan *"sponsors"* interviewed for the January 2010 GAO report indicated a *"limited ability"* to negotiate price concessions with manufacturers for specialty drugs. Consistent with most federal commentary regarding Part D's structure, the GAO apparently did not appreciate that the PBM/specialty pharmacy Defendants and plan sponsors in Part D are typically one and the same. In fact, the GAO only cursorily mentions PBMs in the report, stating: *"Plan sponsors may use pharmacy benefit managers (PBM) to negotiate with manufacturers".*

174. Following this Part D specialty drug analysis, the GAO also sought comment from CMS. As quoted from the CMS letter attached to the end of GAO report: *"GAO reports that, on average, negotiated prices of the sample specialty tier drugs increased by 36 percent between CY 2006 and CY 2009. We would like to note that price increases are not unique to specialty tier drugs. An internal CMS analysis revealed a more than 30 percent increase in the price indices of brand named drugs (both specialty and non-specialty tier drugs) between January 2006 and October 2009".* As such, CMS appeared not particularly concerned about significant specialty drug price increases because all brand drugs in the Part D program had inflated at a similar rate. CMS made no mention of the low level of specialty drug negotiated discounts/rebates in its letter to GAO.

175. The lack of significant concern by CMS regarding severe brand price inflation (for both traditional and specialty drugs) and the low rate of specialty drug manufacturer discounts in the first three years of Medicare Part D is noteworthy. These early pricing and rebate trends were in stark contrast to the agency's own prior expectations. Both the heads of HHS and CMS at the time of Part D's passage expected private competition, driven by aggressive PBM negotiations, to drive considerable brand drug discounts and lower prices for beneficiaries.

BACKGROUND ON BONA FIDE SERVICE FEES (BFSFs)

176. The Relator has been unable to locate any record of legislative discussion of BFSFs prior to Congressional passage of Part D into law. In fact, BFSFs are not even mentioned in the 416-page MMA of 2003, which enacted the Part D program. *PUBLIC LAW 108-173, DEC. 8, 2003.* Furthermore, BFSFs are only cursorily mentioned in the subsequent Code Federal Regulations (CFR) governing the Part D program, in Sections §423.514 and §423.501. Unfortunately, this esoteric item would open the floodgates to vast fraudulent and criminal activity in the Part D program.

177. Section §423.514 establishes the exclusion of BFSFs from rebates, discounts and price concessions. Under *"Reporting requirements for pharmacy benefit manager data"* in Section §423.514, among other reporting requirements, the regulations state: *"Each entity that provides pharmacy benefits management services must provide to the Part D sponsor, and each Part D sponsor must provide to CMS, in a manner specified by CMS, the following: (4) The aggregate amount and type of rebates, discounts or price concessions (excluding bona fide service fees as defined in* §423.501*) that the PBM negotiates that are attributable to patient utilization under the plan".*(emphasis added*)* Consistent with the current fraud allegations, CMS specifically indicates that both rebates/discounts and BFSFs should be linked to patient utilization for a specific Part D plan.

178. Section §423.501 *states: "Bona fide service fees means fees paid by a manufacturer to an entity that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug".*

179. According to CMS, all BFSFs must pass the so-called *"Four-Part Test"* in order to *"qualify"* for exclusion from Medicare Part D *"negotiated price"* calculations. The first three parts of the test are:

a. the *"itemized"* service is actually performed;

b. the manufacturer would otherwise perform or contract for the service in the absence of the service contract, and;

c. the fee is not passed on in whole or in part to a client (in part D, almost always the plan sponsor) or customer of the entity. Important to this complaint, CMS has stated that *"the manufacturers may presume, in the absence of any evidence to the contrary, that the fee paid is not passed on"* (i.e., it is kept by the PBM Defendant or other service providers). *71 Fed. Reg. 69624, 69667-9.*

180. However, the *"Achilles Heel"* facing both the Manufacturer and PBM Defendants in this scheme is the final criteria of the *"Four-Part Test"*, which requires that all BFSFs be paid at *"Fair Market Value"* (FMV) commensurate with an *"arm's length"* transaction between unaffiliated parties.

181. The CMS regulations regarding the handling of BFSFs and the legal requirements of FMV in Medicare Part D have been unequivocally in place since the start of the program in 2006. Furthermore, since at least 2007, the handling of BFSFs and FMV has been virtually identical in the Medicaid, Medicare Part B and Medicare Part D drug programs.

182. In the Part D regulations, CMS places the legal onus on the drug manufacturers to justify that the fees represent *"Fair Market Value" (FMV)* for the services rendered. However, as mentioned previously, the Relator believes that both the Manufacturer and PBM Defendants are liable under the FCA and the AKA for the fraudulent BFSFs and excessive drug costs in Medicare Part D.

183. CMS states: *"manufacturers should appropriately determine fair market value and make reasonable assumptions consistent with adequate documentation that will support their payment for these services at fair market rates sufficient that an outside party can determine the basis for the fair market value determination." 77 Fed. Reg. at 5332.*

184. CMS has purposely kept its guidance regarding FMV vague due to concerns about potential fraud. CMS reiterated its position in its February 2012 proposed rule: *"We continue to be concerned that these fees could be used as a vehicle to provide discounts, as opposed to fees at 'fair market value' for bona fide services. Thus, to avoid potential fraud concerns, we are retaining our definition, but we have chosen not to define 'fair market value' at this time." Federal Register, Vol 77, No 22, February 2, 2012.*

185. CMS has made it clear that it considers all payments to service vendors, other than BFSFs, to be price discounts/concessions that must be included in Part D *"negotiated price"* calculations. As stated in the Medicare Part D DIR *("Direct and Indirect Remunerations"*) Reporting Requirements for 2010 Payment Reconciliation, dated June 6, 2011: *"CMS considers all remunerations received directly or indirectly from pharmaceutical manufacturers, with the exception of bona fide service fees (BFSFs), to be price concessions that serve to reduce the drug costs incurred by the Part D sponsor."*

186. By law, any fee amounts paid by the Manufacturer Defendants to the PBM Defendants and other Service Vendors in *"excess"* of FMV must be reported to CMS as price concessions (i.e., *"Direct and Indirect Remuneration"*) which serve to lower drug costs in Medicare Part D. This requirement was reiterated in CMS's Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, dated June 6, 2011, which states: *"In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4."*

187. Legal precedent *(American Lithotripsy Society v. Thompson, 215 F Supp. 2d 23 (200), US District Court, District of Columbia)* has established that payments in excess of FMV are in effect deemed "*payments for referral*", a violation of the Anti-Kickback Statute.

188. In 2006, CMS enacted regulations clarifying BFSFs. The regulations expressly re-affirmed that service

payments must be for legitimate services rendered and thus not related to the price of the drug. *See Fed. Reg. 69624, 69668 (Dec 1, 2006) (relevant sections codified at 42. C.F.R. 414.802, 414.804).* Since massive price inflation has been the primary factor driving revenue growth for many brand drugs in Medicare Part D, the escalating BFSFs paid to the PBM Defendants in the program related to these drugs are, by definition, primarily tied to price increases (not increased service needs) and therefore illegitimate.

189. In its 2007 final rule, CMS added that BFSFs should be *"associated with the efficient delivery of drugs".* In the rule, CMS interprets the *"Four-Part Test"* to *"encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." 71 Fed. Reg. at 69667-6.* The Relator alleges that greatly escalating fees paid by the Manufacturer Defendants to the PBM Defendants in Medicare Part D, driven primarily by massive price increases in the face of moderating or declining patient volume, fails this CMS *"efficiency"* requirement by a wide margin.

190. The Anti-Kickback Statute also requires that transactions be *"commercially reasonable". 69 Fed. reg. 16,093 (March 26, 2004)* According to the Statute's theory, most business transactions must be commercially reasonable or there would be no reason for them to occur.

191. Furthermore, the Anti-Kickback Statute considers commercial reasonableness to be a separate and distinct process from whether a transaction is established at FMV. The Anti-Kickback Statute states: *"If compensation is based upon comparables, assurance is required that the markets are not "distorted" and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". OIG Supplemental Compliance Program for Hospitals, p 4866-67.*

192. The Relator alleges that the Manufacturer Defendants are using *"comparable", "Market Approach/Percent of Revenue*" service contracts in Medicare Part D with the PBM Defendants and their specialty pharmacy subsidiaries. The *"Market Approach"* utilized by both Defendant parties in the transaction is fraudulent under the Anti-Kickback Statute because of collusive, anticompetitive pricing

activity in the US drug marketplace.

193. The Anti-Kickback Statute also separately requires that, in any compensation arrangement, the payment must represent *"reasonable compensation". 26 C.F.R. 1.162-7 (b) (3) (2004).* The Relator alleges that the excessive fees paid by the Manufacturer Defendants, based upon collusive market pricing, fails this Anti-Kickback requirement by a wide margin. In the Relator's estimation, the Manufacturer Defendants have provided the PBM Defendants with greatly escalating fraudulent BFSF payments in Medicare Part D since the start of the program, despite moderating or declining service needs for their respective products.

194. The CMS *"Four-Part Test"* requirement for manufacturers to *"itemize"* BFSFs by individual product and service is also a key factor in this case. While CMS has not placed direct BFSF reporting requirements on drug manufacturers in Medicare Part D (BFSFs are reported to CMS by plan sponsors), manufacturers must provide considerable BFSF detail if requested by Federal authorities. The Manufacturer Defendants must produce documentation of individual services actually provided by PBM Defendants for specific products and the FMV assessment methodology used to assign appropriate value.

195. Indicative of rising government concern regarding potential BFSF fraud, CMS has steadily increased both BFSF and *"Direct and Indirect Remuneration, (DIR)"* reporting requirements for Part D plan sponsor entities in recent years.

196. Most notably, starting with the 2010 Part D plan year, plan sponsors were required to report all BFSFs received from manufacturers to CMS. In the DIR document, CMS stated *"Any bona fide service fees that are received in connection with the Medicare Part D program and are not included in rebate administration fees must be reported in this column (i.e., column in the DIR entitled "All Other Bona Fide Service Fees"). Final Medicare Part D DIR Reporting Requirements for 2010 Payment Reconciliation: Summary Report, June 6, 2011*.

197. Furthermore, starting with 2010, CMS increased the plan sponsor requirements for BFSF documentation and FMV assessment, stating: *"Part D sponsors must describe the services provided for any bona fide service fees that are not rebate administration fees and the allocation methodology used to determine this amount"*. The document further states *"In the case of rebate administration fees or other amounts from pharmaceutical manufacturers that exceed fair market value, but otherwise meet the definition of a bona fide service fee, the differential between the rebate administration fee or other amount and fair market value must be reported as DIR in column DIR #4"*. Of note, *"rebate administration fees"* are a form of BFSF that, according to the Relator's investigation, has never been specifically defined by CMS.

198. For Part D plan year 2012, CMS added further BFSF FMV requirements, stating: *"Documentation of the fair market value analysis needs to be maintained by the sponsor."*

199. Also starting with the 2012 plan year, CMS requires that *"Part D sponsors report DIR data at the plan level and at the national drug code (NDC) level."* An NDC is an 11-digit identifier that represents a specific manufacturer, product and package size. *CMS Final Medicare Part D DIR Reporting Requirements for 2012, June 7, 2013.* The Relator alleges that fraudulently-inflated PDE reports have been submitted as claims for payment in this scheme. In addition, the specific product reporting requirements starting in 2012 have likely led to detectable DIR fraud by the PBM Defendants in their role as Part D plan sponsors.

200. While recently enhanced CMS reporting requirements may help in the detection of specific BFSF abuse, the data still has important limitations. First, virtually all BFSF and DIR reporting is still done by the plan sponsor "insurance" legal entity in Part D. To this day, CMS does not require direct reporting of BFSFs, or their FMV justification, by drug manufacturers. Furthermore, CMS apparently also does not require direct reporting of BFSFs by PBM or specialty pharmacy legal entities operating in Part D. As such, the PBM Defendants could potentially conceal fraudulent BFSFs in their legally-separate, but wholly-controlled PBM and specialty pharmacy subsidiaries. As noted previously, the Relator believes such concealment would constitute fraud due to the clear payment certification requirements for both plan sponsors and FDRs in Part

D.

201. Second, prior to 2012, DIR and BFSF data was reported by sponsors to CMS only at the *"aggregate"* Part D plan level, not for specific products. CMS requires each plan sponsor to apportion DIR amounts (i.e., primarily manufacturer rebates and fees) in a *"reasonable manner"* of their own choosing among its various plans, both in the public and private sector. As such, the PBM Defendants have full discretion as to how they apportion rebates/discounts and BFSFs from manufacturers among insurance plans, in Part D and the private sector, thus creating further opportunity for deceit.

202. The Relator postulates that the *"aggregate"* limitations of DIR data has hindered detection of the alleged BFSF fraud by CMS, with its primary role to identify Part D plan *"outliers"* for further investigation. As stated in a GAO report released on October 30, 2008: *"among plans with similar characteristics, officials compared plans' reported DIR data in relation to their total drug spending to determine whether any reported DIR seemed particularly high or low….where they found inconsistencies, officials contacted the sponsors to determine whether the inconsistencies could be reasonably explained." GAO Report, GAO-08-1074R, 10/30/08.* Unfortunately, because massive price inflation for the brand drugs in this case has been virtually lock-step and uniform in Part D plans across the country since the 2006 start of Part D, there have not been *"outliers"* to raise suspicion.

203. Due to the complexities of PBM Defendant functionality in Part D and the limitations of BFSF/DIR reporting, the Relator avers that considerable diligence will be required in investigating fraud with these sophisticated Defendants. Fortunately, the clear legal requirements regarding BFSF and FMV in Part D overcome the program's reporting limitations.

204. Given the varied opportunities to obscure illegal BFSF payments, the Relator concluded that an investigation should include a review of all economic transfers between the Manufacturer and PBM Defendants, starting with their contractual arrangements. The Relator would seek to obtain all forms of

economic transfer from the manufacturers to the PBMs and their affiliates, including BFSFs, discounts, free goods, cost-sharing offsets, etc.

205. If the drug product-specific payments/economic transfers from a particular Manufacturer Defendant to a particular PBM Defendant have greatly increased despite a significant moderation or decline in patient drug use, fraud is highly likely. If the payments have primarily been in the form of service fees (typically as a percent of severely inflating drug prices), the Relator would be highly confident of BFSF fraud.

206. The investigation could comprise a relatively straightforward review of manufacturer/PBM contracts or require greater scrutiny of more complex arrangements. The Relator would then seek to separate BFSF payments by the various channels: commercial, Part D, etc. The clear Part D legal requirements for manufacturers to itemize BFSF payments and services by product, as well as to provide FMV justification, should enable identification of the fraud. Defendant disclosures and government data would likely lead to numerous other areas of investigation, such as Patient Assistance Programs (PAPs), the Part D bid/reconciliation process, as well as contracts/arrangements between affiliated PBM Defendants and subsidiaries.

207. For the majority of the products in this case, the Relator expects discovery to detect a wide discrepancy between fast-rising *"percent of revenue"* BFSFs (driven by severe drug price increases) and legitimate volume-based service needs. However, some Manufacturer and PBM Defendants may be using unique mechanisms, other than solely *"percent of revenue"* arrangements, to hide these fraudulent economic transfers from detection.

BACKGROUND ON FAIR MARKET VALUE (FMV) OF BFSFs

208. With CMS purposely not defining methods for BFSF FMV assessment in the Part D program, each drug manufacturer must determine its own process based upon acceptable practices in the private marketplace.

Although FMV assessment in the business world is designed to provide flexibility, an extensive review of the area reveals remarkable consistency in recommended approaches across both private and government entities.

209. The definition of FMV provided by the American Society of Appraisers has been generally accepted by both private industry and government agencies: *"The price expressed in terms of cash equivalents, at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arm's length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts". American Society of Appraisers Business Valuation Standard Glossary, Approved June 2005, Copyright 2005, American Society of Appraisers.*

210. Pertaining to this Qui Tam case, neither CMS nor the vast majority of private payer clients have *"reasonable knowledge of the relevant facts."* The Manufacturer and PBM Defendants have not disclosed the true nature and magnitude of their service fee arrangements to payers.

211. In the private sector, generally accepted valuation principles employee three primary approaches to FMV assessment: the *"Income", "Market"* or *"Cost"* approaches.

212. Using the *"Income Approach*", the FMV payment would be based upon the amount and timing of cash flows generated by the business, asset or service. The *"Income Approach"* is typically not relevant in services provided by healthcare professionals (i.e., including PBM service agreements with manufacturers) because "*these services cannot, and should not be, directly associated with cash flow." Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012.* As such, the Relator's review indicates that use of the *"Income Approach"* is not appropriate for most of the supportive (rather than income generating) services provided for manufacturers by PBMs/specialty pharmacies within Medicare Part D under typical

service agreements. This conclusion was verified by presentations and commentary at the October 2013 FMV BFSF conference.

213. In the *"Market Approach"*, FMV is determined by looking at the market prices of similar services. As such, within Medicare Part D, a manufacturer may decide to determine the FMV of a service arrangement with a PBM/specialty pharmacy based upon the financial terms of competitor manufacturer/vendor relationships.

214. *A "percent of revenue"* arrangement is the most common form of *"Market Approach"* FMV methodology. However, as noted previously, some Manufacturer and PBM Defendants may be utilizing other contract terms, such as flat fees, in their fraudulent BFSF arrangements with PBM Defendants, in part to avoid legal issues pertaining to *"percent of revenue"* arrangements.

215. The "*Market Approach"*, including *"percent of revenue"* constructs, carries significant risk under the Anti-Kickback Statute. These concerns were summed up in a 1992 letter from the OIG to the IRS: *"Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid fair market value. The fact that a buyer in a position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase." Letter from D. McCarty Thorton, Associate General Counsel, Office of Inspector General (HHS) to T. J. Sullivan, Technical Assistant, off of the Associate Chief Counsel, Employee Benefits and Exempt Organizations, December 22, 1992*.

216. In the *"Cost Approach"*, the FMV of the service is based upon the cost of providing the service, plus a reasonable profit. In this methodology, the FMV should not exceed the cost to obtain substitute service from a third-party in an *"arm's-length"* transaction.

217. The Anti-Kickback Statute further states, *"If compensation is based upon comparables, assurance is*

required that the markets are not "distorted" and that compensation is "commensurate with the skill level and experience reasonably necessary to perform the contracted service". OIG Supplemental Compliance Program for Hospitals, p 4866-67. The Anti-Kickback Statute also cautions that FMV carries a risk of fraud if there are *"direct or indirect ties between compensation and Federal healthcare program reimbursement." 42 U.S.C. §1320a-7b(b).*

218. The use of external FMV consultants, a common industry practice, does not protect manufacturers from fraud risk exposure. According to the American Health Lawyers Association, *"Parties should also carefully recognize the fact that commercial reasonableness is often outside the scope of most expert opinions of fair market value, insofar as many internal and outside appraisers do not have sufficient qualifications or information about the transaction to make an informed business judgment regarding its commercial reasonableness without a separate and detailed inquiry into the business (and often clinical) aspects of the transaction or contractual arrangement." Gregory D. Anderson CPS/ABV, CVA Horne LLP, Fair Market Value: What's Fair and is it Commercially Reasonable?, American Health Lawyers Association Annual Meeting, June 27-29, 2011.*

219. Based upon his investigation and public commentary, the Relator concluded that most external FMV and legal experts typically lack the clinical expertise to properly assess the competitive dynamics in the US drug marketplace. Given these legal concerns, healthcare FMV consultants typically suggest that *"companies should not rely on payments made by their competitors in the industry as they may not represent fair market value. Rather, I estimate a market rate using the market compensation for individuals with the qualifications needed to perform the services, adjusted to reflect a consulting rate by adding overhead costs and profit.*" This quote came from a 2012 article by Navigant Life Sciences, a leading FMV consultant serving the pharmaceutical industry. *Helman, Saul B, DeLong, J., Navigant Life Sciences, "Fair Market Value is Critical in Implementing the Physician Payments in Implementing the Physician Payments Sunshine Act", 2012*.

220. Investigation and direct expert commentary clearly indicate that the straightforward *"Cost Approach"* is

the most appropriate and accurate way to assess the FMV of service fees paid by manufacturers to PBMs and specialty pharmacies in the Medicare Part D program. First, FMV experts clearly state that FMV payments should be determined for a *"service and not a person"*, as quoted from the Navigant Consulting article cited above. In a September 2012 presentation, consultants from Huron Associates stated: *"Once a fair market value range for an activity is determined, the amount should be multiplied by the volume of that activity for each type of service and added together to arrive at a fair market value range for the contract." Huron Life Sciences Presentation, "Determining the Bona Fide Nature of Fee-for-Service Arrangements", 9/27/12.*

221. Huron Life Sciences further verified that the *"Cost Approach"* is the preferred methodology for valuing *"bona fide"* services. In a slide from the same presentation cited above, Huron states that the *"price for a bona fide service"* can be thought of as an amount that covers:

a. the direct cost of the service;

b. the overhead associated with delivering that service;

c. the cost of assets used up in the delivery of the service; and,

d. *a reasonable return on the assets employed in the delivery of that service".*

222. A review of standard financial practices regarding the *"Cost Approach"* indicates acceptable *"rate of returns"* in the 10-15% range for *"arm's length transactions"* across numerous industries. Using stable *"percent of revenue"* service contract rates, the Relator estimates that BFSF payment have increased 3-6 fold for most Manufacturer Defendant drugs, despite moderating or declining patient usage. In the Relator's view, these payments are far in excess of a *"reasonable rate of return"*, representing a fraudulent FMV assessment.

223. Recent SEC filings of the largest remaining independent specialty pharmacy, Diplomat Pharmacy, Inc., verify that the appropriate *"arm's length"* compensation to the PBM Defendants for providing manufacturer services should be very modest, even for *"complex"* specialty drugs. In comparison to the larger PBM Defendants, Diplomat has apparently historically lacked the negotiating leverage with drug manufacturers that would enable favorable *"percent of revenue"* service contract arrangements.

224. Despite offering specialty pharmacy services to manufacturers which they claim to be equal to, if not superior to, the PBM Defendants, Diplomat disclosed in its Form S-1 file with the SEC on July 3, 2014 for its Initial Public Offering (IPO) that the company received minimal compensation from manufacturers for these services. As per page 18 of the S-1, Diplomat states: *"We also provide a significant amount of direct and indirect services for the benefit of our pharmaceutical manufacturer customers and our patients in order to get access to specialty drugs, and our failure to provide services at optimal quality could result in losing access to existing and future drugs. In addition, we incur significant costs in providing these services and receive minimal service fees in return."* (Emphasis added)

ISSUES RELATED TO *"PERCENT OF REVENUE"* BFSF CONTRACTS

225. The Relator's investigation indicates that the shift to *"percent of revenue"* service contracts between drug manufacturers and service vendors was initially driven by industry dynamics, rather than regulatory or legislative action. Before 2004, wholesalers and other drug intermediaries made significant profits by *"forward buying"* ahead of manufacturer price increases. *"Forward buying"* is the purchase of drug inventory from manufacturers at one price with the hope to benefit by selling the inventory for greater profit after a price increase. Starting around 2004, drug manufacturers began demanding that drug distributors return these *"forward buying"* profits, in order to normalize inventory/buying patterns. As a result, manufacturers and service vendors began entering into service agreements in which service vendors began charging fees for *"services"* that they previously provided for free (i.e., received indirect compensation via *"forward buying"*), such as distribution services, warehousing, etc. In these service agreements, the fees are generally calculated as a *"percent"* of manufacturer product sales sold to the service vendor.

226. Several important caveats must be considered in applying the genesis of *"percent of revenue"* arrangements to the current Qui Tam case. First, when these arrangements initially arose, all significant government outpatient drug programs (Medicaid, Veteran's Administration, etc.) had regulations preventing

price increases greater than the level of inflation. As such, prior to Part D, increased government program service fee payments by manufacturers for any particular drug were primarily linked to increased volume and patient utilization, not price increases.

227. However, the criminal and fraud risk related to *"percent of revenue"* service contracts greatly escalated with the advent of Medicare Part D, which placed no restrictions on drug price inflation in the program. Prior to Part D, manufacturer *"service contracts"* were apparently a minor part of the PBM business model. As recently as 2003, the largest PBM, Medco Health Solutions, garnered more than 100% of its profits from *"retained"* manufacturer rebates, not from service fees or other means.

228. OIG Compliance Guidelines and Safe Harbors clearly indicate that Manufacturer and PBM Defendant service fee arrangements carry a high risk of fraud. While *"percent of revenue"* service contract terms have never specifically been prohibited, both government and FMV experts have frequently expressed concern that this type of contract structure could lead to fraud, particularly when linked to drug price increases.

229. On April 18, 2003, the OIG issued a document in the Federal Register entitled *"OIG Compliance Program Guidance for Pharmaceutical Manufacturers"* In the document, OIG states: *"In addition, manufacturers may contract with purchasers to provide services to the manufacturer, such as data collection services. These contracts should be structured whenever possible to fit in the personal services safe harbor; in all cases, the remuneration should be fair market value, for legitimate, reasonable, and necessary services"* Further details are provided in the *"Personal Services and Management Contracts Safe Harbor". §1001.952.*

230. Specifically regarding PBMs, the April 2003 Pharmaceutical Manufacturer guidance states: *"Any rebates or other payments by drug manufacturers to PBMs that are based on or otherwise related to, the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO Safe Harbor at 42 CFR 1001.952(j).* GPOs are organizations that act as

purchasing intermediaries that negotiate contracts between health care providers (primarily hospitals) and vendors of medical products and services, including manufacturers, distributors and other suppliers. In the Relator's view, BFSF payments driven primarily by price increases, by definition, are *"based on or otherwise related to, the PBM's customers' purchases."*

231. According to the Relator's investigation, the GPO safe harbor appears to be the only federal mechanism affording specific protection for *"service"* fee contracts structured as a *"percent of manufacturer/vendor revenues"*, albeit with significant limitation. According to the April 2003 manufacturer guidance, "*That safe harbor (GPO) requires, among other things, that the payments be authorized in advance by the PBM's customer and that all amounts actually paid to the PBM on account of the customer's purchases be disclosed in writing at least annually to the customer."* This information must also be disclosed to the Secretary of Health and Human Services (HHS), upon request. With consent of the entity (i.e., payer client), the GPO Safe Harbor states: *"participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor."*

232. The service fee contract arrangements between the Manufacturer and PBM Defendants clearly operate outside these OIG Safe Harbors. Pertaining to the *"Personal Service Safe Harbor"*, the massive increase in BFSF compensation primarily due to extreme price inflation for moderating or declining usage drugs is far in excess of required FMV and is far from reasonable compensation. Investigation as part of this Qui Tam case could also indicate that many of the claimed PBM services provided to the Manufacturer Defendants were not legitimate or necessary.

233. The conflicts with the GPO Safe Harbor are also considerable. While the GPO Safe Harbor does permit *"percent of revenue"* service contracts up to 3% of the purchase price (which would include price increases), the GPO structure requires a written agreement with payer clients and full disclosure to payers annually of the amount of payments from each manufacturer/product vendor. First, the Relator's investigation indicates

that, in many contractual arrangements with private insurance clients, the PBM Defendants are garnering manufacturer service fees far in excess of the 3% of purchase price GPO limit. Second, neither the Manufacturer nor PBM Defendants are fully disclosing either the terms of these contracts or the amounts of BFSFs to CMS in Part D.

234. On October 24, 2014, the GAO issued a report, entitled *"Group Purchasing Organizations, Funding Structure has Potential Implications for Medicare Costs." GAO-15-13.* This report is the sixth that the GAO has issued over the past 12 years following investigations, at the request of Congress, into potential conflicts and fraud concerns related to GPOs. The most recent report specifically sought to determine the impact of the GPO *"percent of revenue"* funding structure on Medicare pricing and costs. As per the document, *"the GPO funding structure protected under the safe harbor has raised questions about whether GPOs are in fact negotiating the lowest possible prices for their customers because of an inherent conflict: while GPOs represent the interests of health care providers to obtain needed products and services at a lower price, they are funded based on a percentage of the costs of products purchased from the vendors they negotiate with on behalf of providers."*

235. Some experts interviewed as part of this recent GAO investigation indicated that GPOs have an incentive to negotiate higher prices for products and services because GPO compensation increases as prices increase. However, the GAO made no definitive conclusions in the report, claiming a lack of *"empirical"* evidence regarding the impact of the GPO funding structure on Medicare costs and prices, despite the nearly 30 years since the passage of the Safe Harbor. The GAO report provides no discussion of pricing trends for GPO clients, either in aggregate or by healthcare sub-segments (such as hospital supplies, devices, drugs, etc.)

236. On the positive side, the potential for fraud on the GPO industry is likely diminished by both the increasing negotiating leverage of hospital clients, as well as the extensive fee disclosure requirements required for Safe Harbor protection. As is widely known, the hospital industry has been experiencing accelerating consolidation in recent years, leading to greater negotiating leverage with GPOs. With these

factors, the five large GPOs surveyed as part of the GAO investigation disclosed that the rate of GPO fees were very modest, averaging 1-2% of product sales. Furthermore, 70% of these GPO administrative fees were "*passed on*" to their customers in 2012. *Group Purchasing Organizations, Funding Structure has Potential Implications for Medicare Costs, GAO-15-13.*

237. The GPO situation contrasts sharply with that of the PBM Defendants, which have dominated Medicare Part D since the 2006 start of the program. Notably, despite the routine use of *"percent of revenue"* service contract terms by PBMs and documented severe Part D specialty/brand drug price inflation, public federal scrutiny of PBM/manufacturer relationships has apparently been minimal since the start of the program.

238. For several reasons, the *"percent of revenue"* fraud risk with PBMs in Part D (and the private sector) is far greater compared to GPOs. First, CMS, the primary *"payer client"* of the PBM Defendants in Part D, is legislatively prevented from negotiating drug prices or limiting price inflation. Second, the full extent of manufacturer/PBM BFSF contract arrangements and payment amounts are not being disclosed to or shared with CMS or private payer clients. In fact, both the Manufacturer and PBM Defendants have actively sought to hide the nature of these arrangements from CMS and private payers.

JUSTICE DEPARTMENT PRECEDENTS REGARDING FMV BFSF FRAUD

239. Prior US Justice Department case precedents pertaining to both PBMs and drug manufacturers appear to provide definitive legal support regarding the FMV of BFSF fraud allegations in this Qui Tam case. These precedent cases pertain to federal drug programs other than Part D, primarily Medicaid and Medicare Part B. To the best of the Relator's knowledge, his Qui Tam filings are the first targeting BFSFs in Medicare Part D.

240. In a prior Settlement agreement with the PBM AdvancePCS, the US Department of Justice has already alleged that manufacturer service fee payments in excess of FMV paid to AdvancePCS were both false claims and kickbacks. On September 7, 2005, a Settlement Agreement was entered into between the United States, Advanced PCS and three Relators (Brown (CA 02-9236), Waite (CA 02-9236) and Schulmann (CA 03-5425). In the Settlement, AdvancePCS paid the sum of $137.5 million to resolve allegations brought forth by the US government. Of note, on March 24, 2004, Advance PCS became a wholly-owned subsidiary of Caremark Rx, Inc. Subsequently, on March 22, 2007, Caremark Rx merged with CVS to form CVS Caremark, one of the largest PBM Defendants in this Qui Tam case.

241. As per the Advance PCS Settlement document: *"The United States alleges that during the period January 1, 1996 through January 27, 2004, AdvancePCS allegedly solicited and/or received payments of (a) administrative fees from pharmaceutical manufacturers for services related to the negotiation and administration of rebate contracts with those manufacturers. and (b) fees for products and services agreements from pharmaceutical manufacturers for the provision by AdvancePCS to those manufacturers of pharmacy or medical data, outcomes research studies, RxReview and Clinical Consulting services, and Resolve 500 programming and data."*

242. The settlement document further states: *"The United States also alleges that to the extent that the payments exceeded the value of the above-referenced services and products, AdvancePCS knowingly caused false claims to be made to OPM and false Medicare claims to be made to HHS. In addition, the United States alleges that AdvancePCS knowingly caused false Medicare claims to be made to HHS in connection with soliciting and/or receiving kickbacks in the nature of payments exceeding the value of the above-referenced services and products."* The Department of Justice made similar manufacturer service fee fraud/kickback allegations in a 2006 Settlement Agreement with another PBM, Medco Health Solutions. Medco merged with PBM Defendant Express Scripts in April 2012.

243. More recently, the US Justice Department included allegations of apparent service fee fraud in the 2012 Settlement Agreement with drug manufacturer, Amgen. As stated in the December 10, 2012 Settlement Agreement: "*During the period from January 1, 2001 to September 30, 2011, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and/or the False Claims Act, 31U.S.C. § 3729, et seq., Amgen offered or paid, or caused to be paid directly and indirectly through Amerisource Bergen Specialty Group, Amerisource Bergen Corp., Cardinal Health Specialty Pharmaceutical Distribution, International Nephrology Network, International Oncology Network, Onmark, National Oncology Alliance, Oncology Supply, Inc., and Oncology Therapeutics, Inc., to health care providers, including, physicians, pharmacists, physician organizations, hospitals, managed care organizations, and group purchasing organizations and physician practice management organizations, remuneration, specifically in the form of cash, free product, free samples, product overfill, dinners, travel, hotels, consulting fees, education and research grants, free consulting services, free reimbursement support services to assist physicians to secure coverage for Amgen products, improper remuneration disguised as proper discounts and rebates, improperly bundled products, payments for phony data collection studies and information collection programs, honoraria and speaker fees, for the purpose of influencing health care providers' selection and utilization of Aranesp, Enbrel, Epogen, Neulasta, Neupogen, and Sensipar regardless of whether the product was administered, reimbursable by federal health care programs, or medically necessary (the "ParagraphG.4 Conduct")."*

244. Based upon allegations in this case, PBM Defendant CVS Caremark, and its officers, appear to be in violation of the Office of Inspector General (OIG) Corporate Integrity Agreement (CIA) that was signed as part of the AdvancePCS settlement. CVS Caremark agreed to comply with all aspects of the five-year CIA, dated September 7, 2005. As per the document, *"Parent, in order to effectuate the settlement embodied in the Settlement Agreement, has voluntarily agreed to comply with the obligations applicable to its subsidiary, AdvancePCS, as set forth in this CIA."*

245. In the settlement, CVS Caremark agreed to *"create procedures reasonably designed to ensure that each existing and new or renewed Arrangement does not violate the Anti-Kickback Statute and/or the Stark Law*

or the regulations, directives, and guidance related to these statutes." In the CIA, Arrangements included *"every arrangement or transaction whereby compensation or remuneration is received by AdvancePCS from or on behalf of a pharmaceutical manufacturer, including, but not limited to, rebates, regardless of how categorized, market share incentives, commissions, fees under product and service agreements, fees received for sales of utilization data and administrative or management fees.."*

246. While the parent CVS Caremark agreed to comply with the CIA terms, the agreement only required that the created Arrangement *"Procedures"* and *"Database"*, as well as their required independent review, be applied to the AdvancePCS subsidiary. As such, CVS Caremark retained considerable flexibility in obscuring manufacturer financial arrangements within other subsidiaries. The Relator expects a thorough investigation of CVS Caremark, and all its affiliates, to uncover considerable BFSF fraud related to Medicare Part D.

247. The Medco CIA, dated October 23, 2006, included very similar provisions regarding financial arrangements with drug manufacturers. The five-year CIA had expired by the closing of Express Scripts merger with Medco in April, 2012.

REPRESENTATIVE PBM CONTRACTS INDICATIVE OF BFSF FRAUD

Express Script:

248. While Manufacturer/PBM service contracts remain outside the public domain, the Relator has found numerous PBM/payer client relationships that support the fraudulent relationship between the Defendant parties. A good example is the April 2012 PBM contract between Express Scripts and the Oklahoma City Municipal Facilities Authority. *Express Scripts, Inc., Pharmacy Benefit Management Agreement, signed December 10, 2012.* The Relator's investigation has determined that PBM/Client contract terms are highly standardized across the PBM industry, both in Part D and the private sector.

249. The Oklahoma City contract states: *"In addition, ESI provides administrative services to formulary rebate contracted manufacturers, which include, for example, maintenance and operation of the systems and other infrastructure necessary for managing and administering the PBM formulary rebate process and access to drug utilization data, as allowed by law, for purposes of verifying and evaluating the rebate payments and for other purposes related to the manufacturer's products. ESI receives administrative fees from the participating manufacturers for these services. These administrative fees are calculated based on the price of the rebated drug or supplies along with the volume of utilization and do not exceed the greater of (i) 4.58% of the average wholesale price (AWP) or (ii) 5.5% of the wholesale acquisition cost (WAC) of the products.* By definition, these fee calculations are inclusive of any price increases.

250. Express goes on to highlight other fee opportunities from manufacturers in the Oklahoma City contract. The PBM contract further states: *"In its capacity as a PBM company, ESI also may receive service fees from manufacturers as compensation for the performance of various services, including, for example, formulary compliance initiatives, clinical services, therapy management services, education services, medical benefit management services, and the sale of non-patient identifiable claim information. These services are not part of the formulary rebate and associated administrative fees."* As such, the actual service fee payments from some manufacturers to Express Scripts may be considerably higher than the *"4.5-5.5% of sales"* range stated in the previous paragraph.

251. Further increasing Express Scripts' manufacturer fee opportunity, the Oklahoma contract excludes both specialty drugs and its own specialty pharmacies from general contract terms. Exhibit A-1 of the contract states: *"Specialty products will be excluded from any price guarantees set forth in the Agreement. In no event will the Mail Service Pharmacy or Participating Pharmacy pricing terms specified in the Agreement, including, but not limited to, the annual average ingredient cost discount guarantees, apply to Specialty Products dispensed by Curascript".* (i.e., the wholly-owned specialty pharmacy subsidiary of Express Scripts)

252. The contract further states that Express Scripts' specialty pharmacies can make separate fee arrangements with manufacturers. As per the contract: *"ESI has several licensed pharmacy subsidiaries, including our specialty pharmacies. These entities may maintain product purchase discount arrangements and/or fee-for-service arrangements with pharmaceutical manufacturers and wholesale distributors. These subsidiary pharmacies contract for these arrangements on their own account in support of their various pharmacy operations. Many of these subsidiary arrangements relate to services provided outside the PBM arrangement, and may be entered irrespective of whether the particular drug is on one of ESI's national formularies. Discounts and fee-for-service payments received by ESI's subsidiary pharmacies are not part of the PBM formulary rebates or associated administrative fees paid to ESI in connection with ESI's PBM formulary rebate programs."* With these numerous potential manufacturer *"service fee"* revenue streams, the PBM Defendants have the opportunity for vast, non-transparent compensation from manufacturers in both Part D and the private sector, especially for specialty drugs exhibiting severe price inflation.

253. In the Oklahoma City contract, PBM Defendant Express Scripts directly admits its culpability to the alleged BFSF fee fraud. First, the contract states: *"ESI and Sponsor shall comply with all applicable and existing federal, state and local laws, standards, codes, ordinances, administrative regulations and all amendments and additions thereto, pertaining in any manner to the work and/or services provided by this Agreement."*

254. Second, under section 7.13 of the contract, entitled *"Alignment of Interests"*, the agreement states: *"ESI acknowledges and agrees (as represented by ESI's response to Sponsor's RFP (i.e., Request for Proposal) that its business model is to align its interests with those of Sponsor. ESI does not engage in any business with a pharmaceutical manufacturer that is designed to manipulate the price or cost of any Brand Drug or Generic Drug in a manner that adversely impacts the cost to Sponsor of providing pharmacy benefits to Members under this Agreement. In this regard, "adversely impacts" is intended to mean that Sponsor would be required to pay a higher price for a Brand Drug or Generic Drug than the market would otherwise provide if it were not for ESI's business arrangement with such pharmaceutical manufacturer."*

255. In stark violation of this contract language, the client and CMS drug costs for a wide array of brand drugs have been exorbitantly escalated by the collusive fee arrangements between the Manufacturer and PBM Defendants, linked to massive price increases.

CVS Caremark:

256. CVS Caremark/client contracts also indicate fraudulent BFSF service fee arrangements with manufacturers based upon severe price inflation. A clear example is CVS Caremark's May 15, 2008 agreement with the *National Association of Counties.* In a section entitled *"Disclosure of Manufacturer Fees,* this contract states: *"Caremark may receive fees or other compensation from Manufacturers, including, without limitation, administrative fees not exceeding three percent of the aggregate cost of the pharmaceutical products dispensed to participants, and fees for property provided or services rendered to a Manufacturer (which may include providing physicians clinical messages consistent with the Performance Drug List, as defined below). Caremark's specialty pharmacies may also receive fees from the Manufacturers for products and services provided …The term Rebate as used in this Agreement does not include these fees and discounts which belong exclusively to Caremark or Caremark's mail order or specialty pharmacies, respectively."*

257. All reimbursement in the Nation Association of Counties contract was based upon discounts to the Average Wholesale Price (AWP), with no protection from price increases. As such, Caremark's fees from the Manufacturer Defendants' surged along with the severe price increases, regardless of product utilization trends.

258. Caremark provided definitive commentary regarding its handling of manufacturer fees during the 2007 bidding process for a contract to manage pharmacy benefits for the *Maryland State Employee and Retiree Health and Welfare Program*. In this contract, Maryland sought full *"pass-through"* to the State for all manufacturer compensation to the PBM, including rebates and service fees.

259. During the Maryland negotiations, the State asked CVS Caremark to confirm the following contract provision: *"The Contractor (i.e., PBM) selected shall not retain any revenue (attributable to the State's business) from pharmaceutical manufacturers or wholesalers, including, but not limited to data fees, access fees, market share fees, rebates, formulary access fees, administrative fees or marketing grants." Before the Maryland State Board of Contract Appeals, Docket Nos. MSBCA 2544, 2548, & 2565, March 2007.*

260. Caremark replied in writing as follows: *"Caremark agrees to the retail, mail, specialty, market share and rebated components. The following further explains Caremark's positioning on passing through service and data fees: Service fees that Caremark receive from pharmaceutical manufacturers include fees that Caremark may receive in connection with programs offered by Caremark, such as physician or participant education programs; compliance and persistency programs; and communications to healthcare professionals. These fees that are paid to Caremark are not paid to or allocated by Caremark on a client-specific basis. Rather, these fees are paid to reimburse Caremark for its service program offerings. For these reasons, Caremark does not disclose to its clients detailed information regarding service fees received and does not share those with its clients."* (Emphasis added)

261. The Maryland Procurement Officer stated that he *"did not understand Caremark's response"*. He also stated that he found the response to be *"purposely confusing"* and interpreted Caremark's response to mean that *"Caremark was holding back money that he wanted to get for the State"*. Caremark did not provide greater clarity on these statements despite several requests. Maryland, in turn, awarded the Maryland contract to another vendor despite Caremark's being the lowest bid.

262. These CVS Caremark disclosures indicate that manufacturer *"percent of revenue"* service fee contracts are set at a national level and not determined by the specific service needs of clients. In the *"County"* contract, CVS Caremark also certifies that it *"shall not violate the federal anti-kickback statute…with respect to the performance of its obligations under this agreement."*

263. In December 2014, the Relator obtained corroboration of the BFSF scheme during a *"one-on-one"* meeting with the CEO of a mid-capitalization biopharmaceutical company at an investor conference. The company markets a drug for the treatment of a neurologic pain indication. In prior public statements/presentations, the CEO had stated that he expects to increase the US price of his drug by 20% per year for the foreseeable future, in line with similar aggressive price increases instituted for Pfizer's Lyrica, the long-standing, market leading drug in the same therapeutic category. Pfizer and Lyrica are implicated in the fraud in this complaint. When asked about the competitive justification for these severe price increases, the CEO casually stated *"well, PBMs don't make their money off of rebates anymore"*. He said, the *"PBMs make their money off of service fees"* and you just have to *"play ball with them"* to get a contract. He then stated that the typical contract required paying *"3-4% of revenues, which would include the price increases"*. The CEO's commentary is highly relevant to this case because his company had recently announced the successful negotiation of contracts with the three leading stand-alone PBMs, Express Scripts, CVS Caremark and Catamaran for private insurance and Part D formulary access.

264. Centralization of the BFSF financial arrangements, as well as lack of disclosure and transparency, have been essential to avoiding detection of this long-standing fraudulent scheme. This industry strategy has been so effective that the Relator found no public mention (in SEC filings, public presentations, etc.) of the term *"bona fide service fees"* by any of the Manufacturer or PBM Defendants during investigation prior to his initial Qui Tam filing. To this day, the scant public mention of BFSFs remains largely confined to esoteric healthcare industry blogs and highly-specialized conference venues. The Relator has determined that lack of disclosure and transparency, in reality, represents a concerted and willful effort to prevent detection of severe co-dependent fraudulent activity in Part D between the Manufacturer and PBM Defendants.

265. In recent decades, the PBM industry has deflected all legal challenges to their business practices in the private sector, in large part due to the staunch defense of its "*non-fiduciary*" status under federal Employee Retirement Income Security Act (ERISA) regulations. However, in sharp contrast, the PBM Defendants' legal liability in this Part D whistleblower action has been clearly established both by law and legal precedent.

First, in Part D, the PBM Defendants, both those operating as plan sponsor *"insurance"* entities and those operating as subcontractors (PBMs and specialty pharmacies), must "*certify the accuracy, completeness and truthfulness of all data related to payment"*. *CMS 42 CFR § 423.505(k) (l*). Second, Part D plan sponsors must also *"certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste and abuse"*, including the False Claims Act and the Anti-Kickback Statute. *CMS 42 CFR § 423.505(k) (l*). These legal determinations regarding PBMs and other Part D subcontractors were verified by both the Court Orders and US Attorney statements related to another active Qui Tam case, the United States of America, ex. rel. Anthony R. Spay v. CVS Caremark Corporation. (*Civil Action No. 09-4672*)

266. Pertaining to this case, the legal structure of these multi-function PBM Defendants may afford opportunities to shield fraudulent/criminal activity from federal detection. For instance, in Part D, CMS regulations place the primary CMS reporting responsibilities on the plan sponsor *"insurance"* entity, not PBM or specialty pharmacy subcontractors. As such, the Relator recognizes that the PBM Defendants may be employing complex legal and financial/accounting arrangements between related subsidiaries in order to obfuscate the BFSF fraud at the center of this case.

267. Inter-relationships of the PBM Defendants also increase complexity. The PBM Defendants United Healthcare, Humana, Express Scripts and CVS Caremark have full ownership of the PBMs/specialty pharmacies servicing the Part D plans for which they also serve as sponsors. Defendant Wellcare similarly had full control of its PBM/specialty pharmacy functions until late 2014. However, various partnerships among the PBM Defendants further increase concentration and decrease transparency in Part D. In plans sponsored by Aetna, Cigna and Anthem, pharmacy benefits are provided via long-term partnerships with the PBMs CVS Caremark, Catamaran (now part of UnitedHealth Group) and Express Scripts, respectively. In addition, in November 2014, CVS Caremark began providing mail order services for Wellcare.

268. According to SEC filings and management commentary, Aetna, Cigna, Anthem and Wellcare appear to have maintained a significant amount of control over PBM functions, especially key formulary decisions and manufacturer contract negotiations. Public disclosure regarding the contractual arrangements for these PBM Defendant partnerships has been minimal. Close scrutiny of the financial terms and transactions related to these secretive PBM arrangements will be a key part of case discovery. Following is a review of the limited public disclosure regarding the various PBM Defendant partnerships.

269. On April 19, 2009, Express Scripts announced an agreement to acquire the NetRx PBM subsidiary of Wellpoint (renamed Anthem in December 2014) for $4.675 billion. According to the press release: *"the transaction includes a 10-year contract for Express Scripts to provide services to Wellpoint."* According to Anthem's 2014 10-K, *"The Express Scripts PBM services include, but are not limited to, pharmacy network management, home delivery, pharmacy customer service, claims processing, rebate management, drug utilization and specialty pharmaceutical management services. Accordingly, the agreement contains certain financial and operational requirements obligating both Express Scripts and us. The failure of either party to meet the respective requirements could potentially serve as a basis for early termination of the contract."* The potential impact on this partnership of the proposed Defendant Anthem acquisition of Defendant Cigna is yet to be determined.

270. According to the July 27, 2010 press release, Aetna stated: *"Aetna and CVS Caremark today announced they have entered into a 12-year contract to provide Pharmacy Benefit Management (PBM) services that will further enhance value and services for Aetna's customers and members. Aetna will retain its PBM and manage clinical programs, protocols and oversight of its pharmacy benefit operations…In addition, CVS Caremark will manage purchasing, inventory management and prescription fulfillment for Aetna's mail-order and specialty pharmacy operations."* The impact on this partnership of the proposed Defendant Aetna acquisition of Defendant Humana is yet to be determined.

271. As per its 2014 10-K filing, Cigna states: *"In June 2013, we entered into a ten-year pharmacy benefit management services agreement with Catamaran Corporation. Under this agreement, we utilize Catamaran's technology and services platforms, retail network contracting and claims processing."* Regarding the deal, Catamaran's 2014 10-K states: *"The two organizations are partnering on sourcing, fulfillment and clinical services. The partnership combines Cigna's significant clinical management and customer engagement capabilities with Catamaran's innovative technology solutions, while seeking to leverage the two companies' scale of network choice and efficient procurement to deliver value to Cigna's clients and members."* Most indicative of Cigna's ongoing central PBM role, Catamaran states: *"The gross profit percentage related to the Cigna contract is significantly lower than historical gross profit percentages due to the related transaction volume."* The long-term impact of the recently-closed Defendant UnitedHealth Group acquisition of Defendant Catamaran is yet to be determined.

272. On its Medicare website, Wellcare states: *"Effective November 1, 2014, CVS Caremark Mail Service Pharmacy will be Wellcare's new preferred mail-order."* Describing the rationale for the change, Wellcare further states: *"Depending upon your plan, you could save on your prescriptions (excluding our Specialty Tier 5)."* *www.wellcare.com/medicare/mail_order_pharmacy_coverage*.

PRIOR MEDCO SEC DISCLOSURES INDICATIVE OF LONG-STANDING, INTENTIONAL BFSF FRAUD

273. Prior to its 2012 merger with PBM Defendant Express Scripts, Medco Health Solutions was the largest independent PBM operating in the United States. As part of a 2004 settlement of a prior Qui Tam case and a related 5-year Office of Inspector General (OIG) Corporate Integrity Agreement (CIA dated October 2006), Medco provided detailed financial disclosures regarding its PBM operations. In sharp contrast, the current financial disclosures of the PBM Defendants regarding their PBM and specialty pharmacy operations are very limited. Once combined with Express Scripts, detailed Medco financial disclosure also ceased.

274. Medco, for the fiscal years 2003 through 2011, disclosed both overall brand manufacturer rebates, as well as the amount of rebates the PBM *"retained"*. Furthermore, Medco provided greater granularity regarding both the revenues and profitability of its separate PBM (retail and mail combined) and Specialty Pharmacy segments. In the filings, Medco also provided disclosure of its unique contractual relationships with specialty drug manufacturers and its accounting/financial reporting methodologies.

275. The information provided by Medco in its 2003-2011 10-K filings fully corroborates this Qui Tam case.

Specifically, the Medco disclosures indicate:

a. The PBM Defendants, in cooperation with drug manufacturers, intentionally shifted from a *"retained"* rebate compensation model to one based upon manufacturer *"service fees"*. Driven by the unique bona fide service fee (BFSF) incentives (i.e., minimal disclosure, no amount limits, exclusion from Part D *"negotiated price"* calculations), the transition began soon after the 2003 passage of Medicare Part D and was fully in place when the program was enacted in January 2006.

b. Consistent with these Qui Tam allegations, Medco disclosed that its manufacturer *"fee"* contracts are calculated as a *"percent of revenues"*, inclusive of price increases. Furthermore, Medco disclosed unique contract terms with specialty drug manufacturers, which allowed the parties to quickly pass drug price increases on to payer clients, with a related increase in PBM service fees from drug manufacturers.

c. Medco's financial disclosures indicate that brand drug price inflation was the sole driver of revenue growth between 2006 and 2011. The vast majority of the Medco's incremental compensation came via related service fees received from manufacturers. Medco's *"retained"* manufacturer rebates increased minimally between 2006 and 2011, despite a doubling of profits

over the same timeframe.

276. In **Exhibit 24**, we provide the key Medco rebate data and relevant calculations for the years 2003 through 2011. The amount of overall brand drug rebates Medco garnered from manufacturers increased only modestly from $3.0 billion in 2003 (the year the Part D legislation was passed) to $3.4 billion in 2006 (the year the program was enacted). However, the amount of annual rebates *"retained"* by Medco dropped precipitously over the three years. In 2003, Medco *"retained"* 53.6% of the rebates or $1.6 billion. In 2006, Medco *"retained"* only 19.6% or $670 million of the manufacturer rebates, a 58% decline versus 2003.

277. After the passage of Part D, Medco reported a sharp increase in the level of rebates from manufacturers, from $3.4 billion in 2006 to $6.2 billion in 2011, an 82% increase over the five years. However, the proportion of rebates *"retained"* by Medco continued to decrease, with the absolute amount kept by the PBM increasing only modestly between 2006 and 2011. By 2011, Medco *"retained"* only 12.2% of rebates or $757 million.

278. The *"retained"* manufacturer rebates for Medco were highly profitable, likely because they bear little associated operating costs. As per Medco's disclosures, its *"retained"* rebates of $1.6 billion in 2003 accounted for all the company's profits and more - 104.7% of total gross margin profits (i.e., profits before administrative costs). See **Exhibit 24**.

279. As such, the precipitous erosion of *"retained"* rebates in subsequent years would have had a devastating impact on Medco's profitability, without alternative sources of profits. Despite the massive decline in *"retained"* manufacturer rebates, Medco reported astounding overall gross profit growth of 50% from $1.6 billion in 2003 to $2.4 billion in 2006. The company's growth profits grew even stronger between 2006 and 2011, with gross profits nearly doubling over the period to $4.6 billion. Medco's business underwent a vast transformation during this period. Whereas *"retained"* manufacturer rebates accounted for all of Medco's

profits in 2003, they accounted for only 27.9% of gross profits in 2006 and fell even further to 16.7% of gross profits by 2011.

280. In its SEC filings, Medco attributed this business model transformation to shifting client relationships. In its 2011 10-K Medco states that *"the changes in retained rebate percentages are reflective of client mix and the associated client preferences regarding the rebate sharing aspects of their overall contract pricing structure"*. Medco made no mention of Part D or its unique BFSF treatment as contributing factors to the rebate shift.

281. At the time of Part D's passage, Medco was completely dependent upon *"retained"* manufacturer brand drug rebates for its profitability. This fact also indicates that the remainder of Medco's operation, including its generic business, was unprofitable in 2003. As the largest PBM in the US in 2003 by a wide margin, the Medco financials indicate that *"retained"* rebates were the dominant profit driver in the PBM industry at the time. In 2003, Medco had by far greatest generic procurement leverage and the most efficient mail order operations. If Medco's operations in 2003, excluding *"retained"* rebates, were unprofitable, smaller PBMs were either similarly dependent on manufacturers for profits or were minimally profitable at best.

282. Medco attributed robust profit growth between 2003 and 2011, despite eroding *"retained"* rebates, to gains in its generic business. Medco stated in its 2004 10-K: *"the impact on profitability from the increase in generic utilization, particularly in mail order, more than offsets the impact from lower rebate retention on brand name prescriptions."*

283. Medco noted a wider range of contributing factors in its 2006 10-K, stating: *"the gross margin effect of overall higher rebate sharing levels is partially mitigated by other elements of pricing including higher claims processing, administrative and other client service fees, higher generic dispensing rates, and increased specialty volumes."* In its final 2011 10-K, Medco reiterated its ongoing dependence on these same profit drivers, stating: *"Our future success will be largely dependent on our ability to drive mail-order*

volume and increased generic penetration rates in light of the significant brand-name drug patent expirations expected to occur over the next several years." Medco did not mention other forms of drug manufacturer compensation, including service fees, as important profit contributors.

284. The Relator sees a very clear separation between legitimate *"service fee"* payments to PBMs and the fraudulent/criminal compensation at the center of this Qui Tam case. For instance, payer clients pay legitimate service/administrative fees to PBMs for valuable functions such as claims processing and clinical program administration. In most instances, these administrative/service fees are transparent to payer clients, with the payment based upon resources employed, such as labor costs, time and the quantity of services.

285. Manufacturers also pay PBMs for similar legitimate services. However, these straightforward transactions are a completely separate entity from the fraudulent BFSFs in Part D (and the equivalent in the private insurance sector) at the center of this case, which are often being paid with no relation to drug utilization or service needs and driven primarily by price increases.

286. Based upon the company's own financial disclosures, Medco's claims regarding accelerating generic profitability between 2003 and 2011 would appear to be mathematically impossible. Excluding *"retained"* rebates, Medco reported an astounding increase in annual gross profits from a -$71 million loss in 2003 to a $3.9 billion profit in 2011. See **Exhibit 25**. Cumulatively, excluding manufacturer *"retained"* rebates, Medco reported gross profits of $19.3 billion for the 2003-2011 period. With Medco's generic business apparently unprofitable in 2003, the implied vast transformation in the segment defies rational explanation.

287. Further mitigating this transformation, the generic and mail order segments for all PBMs have faced rising competition over the past decade. For one, Medicare Part D decreased *"spread"* opportunities for both brand drugs and generics. In generics, the increased use of *"Maximal Allowable Cost, (MAC)"* pricing, including via State legislation, has also lessened generic profit opportunities. Since March 2013, eight US states have enacted MAC legislation to protect consumers from generic *"spread"* abuse, with legislation

pending in many other states. Finally, the penetration of mail order, a key channel for generics, has also moderated considerably over the past decade due to increased competition from 90-day prescriptions offered by retail pharmacies. Based upon these and other competitive pressures, the Relator sees no viable way that Medco's generic segment could have been the primary driver for Medco's accelerating profitability in the face of lower *"retained"* manufacturer rebates between 2003 and 2011.

288. In reality, the Relator has determined that escalating *"hidden"* service fee compensation from drug manufacturers to PBMs has been the primary driver of Medco's remarkable business transformation and surging profitability between 2003 and 2011. The increased *"spread"* and manufacturer rebate transparency requirements in Medicare Part D left BFSFs as the only mechanism for large-scale *"hidden"* payments between drug manufacturers and PBMs. In order to prepare for Part D, the Defendant parties began a parallel shift in their business model in the private insurance market prior to the 2006 enactment of Part D. The fast transition starting in 2003 at Medco indicates the long standing and intentional nature of the fraudulent BFSF scheme.

289. In its 10-K documents, Medco reported details regarding the components of revenue growth each year between 2006 and 2011 for its separate retail and mail order operations. Medco disclosed that patent expirations and increased generic penetration decreased their corporate revenues by $11 billion cumulatively between 2006 and 2011. See **Exhibit 26**. This fact undermines Medco's claim that its generic business was the primary driver of accelerating profitability between 2003 and 2011.

290. The Medco filings also indicate that brand drug price increases accounted for virtually all of the company's revenue growth between 2006 and 2011. See **Exhibit 26.** For the years 2006 through 2011, Medco reported a cumulative revenue increase of $31.1 billion. Over this timeframe, net brand drug price increases added $29.0 billion to revenues, representing 93% of the company's overall revenue growth.

291. As such, the driver of Medco's vast profit growth between 2003 and 2011 had to be manufacturer service fees linked to this severe brand drug price inflation. As discussed previously, the overall manufacturer rebate percentage in Part D was modest in the 9-11% of program spending each year between 2006 and 2011, despite severe price increases for many specialty and other brand drugs. The Medco filings indicate that the company's overall rebate rate was modestly lower and also stable in the 7.5-8.4% range of revenues throughout the 2003 to 2011 timeframe. See **Exhibit 24**. The stable and modest rebate levels confirm that the vast majority of the financial gains from severe brand price inflation, both in Part D and the private insurance market, accrued to the drug manufacturers and their collusive PBM partners.

292. Medco disclosed that its manufacturer *"service fee"* contracts are calculated as a *"percent of revenues"*, inclusive of price increases. Several of Medco's 10-Ks, including the 2006 document states: *Our contracts with manufacturers provide us with rebates and fees for prescription drugs through our mail-order and retail pharmacy networks, discounts for prescription drugs we purchase and dispense from our mail-order pharmacies, and performance-based fees associated with certain biopharmaceutical drugs. Rebates and fees are generally calculated as a percentage of the aggregate dollar value of a particular drug that we dispensed, based upon the manufacturer's published wholesale price for that drug.* (Emphasis added) *Rebates and fees are generally invoiced to the pharmaceutical manufacturer and paid to us on a quarterly basis."*

293. In its 2006 10-K, Medco also disclosed the unique nature of its contracts with biopharmaceutical manufacturers of specialty drugs. Medco stated: *Our agreement with these suppliers (biopharmaceutical companies) are short-term and cancellable by either party without cause on 60 to 365 days prior notice. These arrangements also generally limit our ability to distribute competing drugs, provide services related to competing drugs, during and, in some cases, after the term of the agreement, while allowing the supplier to distribute through channels other than us. Further, these agreements provide that pricing and other terms of these relationships be periodically adjusted for changing market conditions or required service levels."* (Emphasis added)

294. Medco also disclosed that its purchasing arrangements for specialty drugs typically differ compared with many traditional brand pharmaceuticals. As stated in its 2011 10-K: *We purchase our pharmaceuticals either from our primary wholesaler, AmerisourceBergen, which accounted for approximately 63% of our overall 2011 drug purchases, or directly from pharmaceutical manufacturers. Most of the purchases from our primary wholesaler were for brand-name drugs. Specialty and generic drugs are generally purchased directly from manufacturers."*

295. In the marketplace, both CMS and private payers have typically faced multiple, often large, price increases in a given year, particularly for many high-cost specialty drugs. The flexible nature of Medco's specialty drug manufacturer contracts appears designed such that both parties benefit significantly from price increases of any magnitude and frequency, with the majority of the escalating drug costs "*passed through"* to CMS and other payers. As noted previously in the discussion of the Oklahoma City Express Scripts contract, specialty drugs have historically often been excluded from rebate arrangements and price protection provisions in PBM/client contracts. Medco's direct purchasing arrangements with specialty drug manufacturers, rather than via wholesalers, likely increases the profitability of service fee arrangements for both parties with minimal transparency.

296. Medco also reported a dramatic shift in the types of rebates it received from manufacturers which is consistent to with the increased reliance on service fees for compensation. In its 10-Ks, Medco classified contractual rebates with manufacturers into two types: *"formulary rebates"* and *"performance-based rebates"*. According to the 2005 10-K: *"formulary rebates, which are based on inclusion of the pharmaceutical manufacturer's products on the formularies used by our clients and…and do not subject such products to restrictions which are not applicable to competing brand-name products."* Medco further states: *"performance-based rebates, also known as market share rebates, which are based on our achieving various performance criteria, such as contractually specified market share levels."*

297. Performance-based rebates are the key driver of aggressive brand drug *"therapeutic substitution"* programs. *"Therapeutic substitution"* programs are the primary mechanism employed by PBMs in using their leverage to achieve savings for clients in crowded brand therapeutic categories. Aggressive PBM price negotiation with manufacturers for inclusion in formularies for these programs is also the key to preventing drug price inflation in the crowded brand drug therapeutic categories. In Part D, CMS expected PBMs to receive greater rebates for themselves and their clients by shifting market share to *"preferred"* lower cost brand therapies.

298. With Medco's quick transition to *"service fee"* arrangements with manufacturers, linked to severe price increases, the role of both brand *"therapeutic substitution"* programs and related *"performance-based rebates*" greatly diminished between 2003 and 2011.

299. In 2003, Medco reported that the proportion of rebates was about evenly split between *"formulary"* and *"performance-based"* rebates, at 49.5% and 50.4%, respectively. See **Exhibit 24**. By 2011, *"formulary"* and *"performance-based"* rebates accounted for 87% and 13% of overall rebates, respectively. Medco admitted the shifting nature of manufacturer rebate contracts as far back as its 2005 10-K, stating: *"Pharmaceutical manufacturers have also increasingly made rebate payments dependent upon our agreement to include a broad array of their products in our formularies".*

300. In reality, the shift to *"formulary rebates"* enabled the inclusion of virtually all major brand traditional and specialty drugs in crowded therapeutic categories within increasingly *"open"* formularies. In this collusive scheme, the PBM Defendants were more than willing to *"pass through"* the majority of modest rebates to CMS and private clients, while obtaining greatly escalating compensation from manufacturers via minimally-disclosed service fee arrangements tied to massive price inflation. With BFSFs excluded from Part D *"negotiated price"* calculations, both collusive parties benefited greatly from fast escalating end-user drug prices to the detriment of CMS, their private clients, taxpayers and patients.

301. Medco also used creative accounting methods to hide escalating manufacturer service fees and perpetuate the fraud. In August 2005, Medco acquired Accredo, the largest US independent specialty pharmacy at the time. Following the purchase, Medco greatly increased its scale in specialty pharmacy just of ahead of the January 1, 2006 start of Part D. Coincident with the Accredo acquisition, Medco formed a new division, entitled, Medco *"Therapeutic Resource Centers"* (TRCs), specifically to provide support services for its burgeoning specialty drug operations. However, the TRCs were also responsible for providing support *"services"* for traditional chronic disease drug categories, such as diabetes.

302. However, rather than placing this division within its Specialty Pharmacy Segment, Medco placed the TRC operations within its mail order division in its PBM Segment. As per the 2007 10-K, *"these centers, located within our mail-order pharmacy operations*, (Emphasis added) *are designed around the theory that specialization leads to better pharmacy care for members with chronic and complex conditions and pharmacy needs. To better serve these members and their plans our pharmacists are specialized in chronic conditions that have significant gaps in care and significant costs, such as diabetes, heart disease and management. Specialist pharmacists of a given specialty practice together in center dedicated to the pharmacy care of people with needs in that specialty. Our scale and technology allow us to dedicate entire pharmacy practices to a single specialty and bring the services of our specialist pharmacists to the members who need them, as they need them."* With this accounting, Medco was intentionally seeking to conceal its increasing reliance on manufacturer services fees, particularly for specialty drugs, from CMS, private payers and other constituents.

THE SECRETIVE EVOLUTION OF PBM DEFENDANT PROFITABILITY

303. The PBM industry originated in the 1970's as simple prescription claims processors for health insurers and employers. In this role, PBMs were paid a small fee for each transaction. In the early days, PBMs typically had minimal direct relationships with drug manufacturers.

304. In the 1980's, Pharmacy Benefit Managers (PBMs) saw an opportunity to more aggressively manage drug costs for payers. At the time, US pharmaceutical companies sold predominantly traditional *"pills"* via massive primary care sales forces. During this period, drug costs were skyrocketing because payers had limited ability to offset this massive marketing muscle at a time when drug industry pipeline output was relatively strong, generic alternatives were limited and prices increases were routine.

305. Into this milieu, the nascent PBM industry offered large corporations and health plans cost management techniques for the first time. The PBM industry recognized that, due to limited payer pushback, the pharmaceutical industry had created a considerable amount of redundancy in its product offerings. Because the industry was able to sell virtually any product with enough sales representatives, they developed many low development risk, brand *"me-too"* products in major traditional brand drug therapeutic categories, such as cholesterol-lowering, hypertension and depression.

306. As its client base grew, Medco, the dominant PBM of the early years, proceeded to extract rising price discounts from major pharmaceutical companies seeking market share in crowded brand therapeutic categories *("therapeutic substitution"*). Medco also sought to increase the use of generics *("generic substitution")* where possible. Drug manufacturers that provided greater brand drug discounts were included on Medco's preferred *"formularies"*, while others were largely shut out of its client base. In particular, Medco used its unique, high-efficiency mail order pharmacy capabilities with great success to shift market share towards its preferred brand drugs in the marketplace. Over time, other PBMs arose and grew to serve the US drug management market.

307. During this period, the profit drivers for the PBM industry shifted dramatically. While transaction fees were very modest, the PBM profit opportunity was transformed by the large manufacturer rebate opportunity. In arrangements with manufacturers that were routinely not disclosed to payer clients, the PBMs *"retained"* a significant portion of the negotiated rebates. As note previously, in 2003, Medco *"retained"* 53.6% of manufacturer rebates, which accounted for more than 100% of Medco's profits.

308. These rebate relationships created conflicts-of-interest between PBMs and their payer clients. The potential conflicts further escalated in the early 1990's when the three largest PBMs were acquired by drug manufacturers. Several years later all three leading PBMs were spun out into independent organizations again. Numerous Qui Tam suits alleged that PBMs were favoring certain manufacturer's products to the financial detriment of payer clients. Several major cases were settled by the Justice Department without admission of liability. Numerous lawsuits were also filed by private payers against PBMs. However, these efforts were generally unsuccessful due to the PBM industry's staunch defense of its *"non-fiduciary"* status under ERISA laws.

309. The transformation of the PBM industry has been even more dramatic over the past decade or so. First, Medicare Part D required full disclosure of manufacturer rebates, as well as the portion *"retained"* by PBMs. This transparency would greatly increase scrutiny of manufacturer rebate arrangements by both the government and the private sector.

310. Second, the brand pharmaceutical industry faced a severe economic threat due the patent expirations for many of its blockbuster traditional drugs. Notable blockbuster traditional pharmaceuticals that have lost patent protection since 2006 include: Zocor (cholesterol, 2006), Zoloft (depression, 2006), Imitrex (migraines, 2007), Ambien (sleep, 2007), Norvasc (cardiac, 2007), Risperdal (neurologic, 2008), Topomax (neurologic, 2009), Cozaar (cardiac, 2010), Aricept (Alzheimer's, 2010), Lipitor (cholesterol, 2011), Zyprexa (neurologic, 2011), Diovan (cardiac, 2012), Seroquel (neurologic, 2012), Plavix (cardiac, 2012), Singulair (asthma, 2012), Actos (diabetes, 2012), Lexapro (depression, 2012) and Aciphex (ulcers, 2013). Due to these vast patent expirations, drug manufacturers became increasingly dependent upon their remaining brand drugs for revenue and profit growth.

311. With highly safe and effective generic products now available across all the major primary care target markets, the drug industry's traditional drug pipeline ground to a near standstill. After a period of consolidation and cost-cutting, pharmaceutical companies increasingly adopted the technologies and

business strategies of the burgeoning biotechnology industry. Both industries now primarily focus on developing specialty drugs for severe medical conditions (e.g., cancer, autoimmune diseases, rare genetic disorders) that can garner high pricing and profits with far less marketing costs.

312. Similar to the biopharmaceutical industry, specialty drugs have become the primary driver for the PBM growth and profits. PBM executives have repeatedly verified the evolution of the industry and its increased reliance on specialty drugs. At its sixth annual Investor Day held on November 15, 2012, Dr. Sumit Dutta, the Chief Medical officer of the PBM Catamaran (and a former executive at Medco) stated in a presentation: *"When I first started in the industry, the profit drivers in the PBM industry were rebates on branded manufacturer products. ...and then we saw after that was a wave of profitability from generics....pharmaceutical companies focused on delivering new drugs, me-too drugs, and setting price. And the counterparty to that, or the PBMs, who negotiated rebates, price, created clinical programs to eliminate inappropriate utilization"*.

313. The former Chief Financial Officer of Express Scripts, Jeff Hall, made similar comments at a leading investor conference on January 8, 2013: *"In the early days, our primary tools were retail networks and rebates. We evolved that with innovative tools to drive generics to low-cost brands. We created world-class clinical offerings. More recently, we've developed tools to increase the use of home delivery, improve the cost and quality of specialty drugs"*. In the same presentation Mr. Hall provided a slide indicating that specialty drug spending for Express Scripts clients has grown on average 20% each and every year since 2005. Despite going on to state that specialty drugs are *"one of the top concerns of almost every client we talk to today"*, Mr. Hall, forecasted little change for the future; *"we are seeing 20% plus trend going forward"*.

314. However, in both its SEC filings and public commentary, the PBM Defendants have assiduously avoided specific discussion regarding the nature of its profits generated by specialty drugs. Over the past decade to the present day, the PBM Defendants typically cite increased generic penetration as their largest profit driver. In fact, this PBM industry deception has been so successful that a wide array of external expert continue to

highlight generic *"spreads"* as the industry's key profit source. Numerous recent examples can be found in the expert testimonies from the 2014 ERISA Advisory Council regarding PBM Compensation and Fee Disclosure. http://www.dol.gov/ebsa/publications/2014ACwrittenstatements.html#3

315. The PBM Defendants create additional confusion regarding the profit contribution from generics when describing the profitability metrics of their business. They routinely state that their profits benefit from the *"higher profit margins"* on generic drugs relative to brand drugs. Profit margins equate to the *"ratio"* of profits to sales. However, this measure misrepresents the relative absolute profit contribution. The absolute profits from a *"high margin"*, but low-priced, generic prescription are very modest. In contrast, the absolute profit generated by a *"percent of revenue"* fee for a fast-inflating traditional and extreme-price specialty brand drug is many magnitudes larger.

316. Rather than via generics, the Relator has determined that manufacturer service fees, linked to massive price increases, have been the primary driver of the PBM industry's vast profit growth since the arrival of Medicare Part D. In fact, the PBM industry has been almost entirely dependent upon brand drug manufacturers for its profits for the past two decades. Compensation from manufacturers to PBMs intentionally transitioned from largely undisclosed *"retained"* rebates to largely hidden service fees due to unique incentives in the Part D program.

317. PBM Defendant Catamaran made a definitive disclosure at its November 2012 Investor Day. Catamaran provided visibility regarding the shifting profitability drivers in the secretive PBM industry. See **Exhibit 27**. Catamaran's SVP of Pharmacy Operations, Albert Thigpen stated that Catamaran's profits from a traditional retail prescription had fallen in half between 2008 and 2012. For a traditional mail order drug, Catamaran's profit per prescription had increased very *"modestly"* over the same time frame. Based upon the scale in management's own chart, each traditional mail prescription generated approximately 14 times the profit of a traditional retail prescription in 2012, versus about 7 times the retail profit in 2008.

318. Mr. Thigpen further stated that the profit generated by a specialty drug prescription had vastly improved over the four years, more than *"tripling"* between 2008 and 2012. Based upon management's chart, each specialty drug prescription generated about 6 times the profit of a traditional mail prescription in 2012, up from about a 3-4 times ratio in 2008. Furthermore, the profit generated by an traditional retail prescription for Catamaran in 2012 was minimal compared to that of a specialty prescription. Given Catamaran's small PBM market share (less than 2% of US specialty drug sales in 2011), the expansion of specialty drug profitability has likely been even greater for the larger PBM Defendants.

EXPRESS SCRIPTS REPORTED PART D SPENDING TRENDS ILLUSTRATIVE OF FRAUD

319. Lack of transparency between drug manufacturers and PBMs has been essential for promulgating the long-standing and systemic BFSF fraud outlined in the Relator's Qui Tam cases. As such, the majority of the PBM Defendants disclose little regarding the drug spending and pricing trends within their customer base. Fortunately, PBM Defendant Express Scripts does provide data in its annual *Drug Trend Reports* that confirms the severe pricing fraud. The Express Scripts *Drug Trend Reports* dating back to 2003, can be found at the following link: http://lab.express-scripts.com/drug-trend-report/previous-reports. Starting with its 2010 *Drug Trend Report*, Express Scripts began providing limited disclosure specific to its Medicare Part D operations.

320. Less-detailed public data from other PBM Defendants indicates that Express Scripts' trends are highly-indicative of broader PBM Defendant trends. In April 2014, Defendant UnitedHealth Group released an issue brief, entitled, *"The Growth of Specialty Pharmacy"*. In the report, UnitedHealth indicated the uniform nature of specialty drug spending trends among the PBM Defendants. The report states: *"One analysis shows per capita growth rates ranging from 14 percent to 20 percent a year for specialty drugs in the commercial market for the three largest pharmacy benefit managers. Estimates for near-term cost growth suggests those trends will continue, ranging from 13 percent to 25% per-member-per-year for all payors." UnitedHealth*

Center for Health Reform & Modernization, "The Growth of Specialty Pharmacy", Issue Brief, April 2014. UnitedHealth also noted the greater impact of specialty drugs on Medicare, stating: *"Specialty drugs particularly impact Medicare beneficiaries, who have relatively high spending (on a per person basis) for those drugs, about double the amount of spending by commercial health plan members."*

321. Express Scripts and other PBM Defendants typically place a disclaimer on any public drug spending disclosures, claiming that the data may not include rebates/discounts from manufacturers. However, the Relator has already established the modest level of rebates in Part D and minimal retention of any rebates by the PBM Defendants. As such, the reported Express Script Medicare Part D trends are instructive in analyzing the fraud outlined in this complaint.

322. In the *"percent of revenue"* BFSF model at the center of this case, the Manufacturer and PBM Defendant parties are mutually-dependent upon Part D revenue growth, driven by either volume or pricing. However, Express Script's own data indicate that volume growth in the US Part D program has been very modest in recent years, both in the traditional drug and specialty drug segments. See **Exhibit 28**. At Express Scripts, utilization for traditional drugs has increased only an average of 3% per year between 2010 and 2014. This increase is modestly higher than the average 1-2% utilization increase reported by IMS for the overall US prescription market. Economic conditions and rising patient cost-sharing requirements are typically cited as key factors in moderating US healthcare utilization, including for drugs, in recent years.

323. Similarly, regardless of industry rhetoric, the actual utilization growth in Medicare of specialty drugs has also been modest. Within Express Script's Medicare business, reported specialty drug annual utilization trends have been volatile, ranging from -2.7% in 2012 to +11.6% in 2014, with the latter year impacted by surging hepatitis C drug usage. Even including the temporary hepatitis C effect, Express Scripts has reported modest average annual increases in Medicare specialty drug utilization of 4.9% between 2010 and 2014.

324. With a wide array of patent expirations, many traditional US drug categories have seen significant price erosion, both in the private sector and Medicare Part D. In Part D, Express Scripts reported an annual -2.2% to -3.7% trend contribution from pricing for traditional drugs between 2010 and 2013. Even with a surge to positive 6.4% price impact in 2014 (primarily due to severe diabetes drug price increases), the annual contribution from pricing for Part D traditional drugs averaged -1.3% between 2010 and 2014. See **Exhibit 28**.

325. With modest volume trends (for both traditional and specialty drugs) and eroding traditional drug prices, many drug manufacturers and the entire PBM industry have been primarily dependent upon specialty drug price inflation for growth. Within Express Script's Medicare business, specialty drug price inflation has been massive in recent years. Express Scripts has reported an average Part D annual trend contribution of +25% from specialty drug pricing between 2010 and 2014. Furthermore, the contribution from specialty drug pricing has markedly accelerated from a +10% average impact in 2010-2011 to an average +25% effect in 2012-14. See **Exhibit 28**.

326. The $11 billion increase in US hepatitis C drug spending in 2014 was a key factor in Express Scripts' reported 46% surge in Medicare Part D specialty drug spending, as well as the +34% reported contribution from rising drug costs. The PBM Defendants no doubt have received significant service fees related to hepatitis C drugs and new specialty drugs launched in recent years.

327. However, excluding the impact of hepatitis C drugs in 2014, Express Scripts' Part D specialty drug spending grew 27% in 2014, with virtually all of the increase driven by price inflation. As such, the majority of specialty drug spending growth since the start of Part D has to have been driven by BFSF-related fraudulent price inflation for older specialty drugs, not new product launches.

328. The wide array of traditional patent expirations in recent years has led to a concentration of BFSF-related pricing fraud into a handful of major remaining brand drug therapeutic categories. In the traditional drug

segment, spending trends for 4 of the 5 largest drug categories, namely antihypertensive, cholesterol-lowering, ulcers and antidepressants, have eroded sharply in recent years due to patent expirations. Express Scripts reported that Medicare Part D spending for its high cholesterol, high blood pressure/heart disease, mental/neurologic disorder and heartburn/ulcer categories, declined an average of -2.1%, -6.3%, -5.9% and -6.7% per year, respectively, between 2010 and 2014. See **Exhibit 29**.

329. With these prior top-spending categories in decline, the diabetes segment remains the only top-five traditional US drug category still dominated by brand drugs. In Express Script's Medicare population, diabetes drug spending has risen by an average of 15% per year between 2010 and 2014, despite only 4.8% average utilization growth. See **Exhibit 29**. Price inflation has accounted for 60% of diabetes category growth on average each year in Express Scripts Medicare segment between 2010 and 2014. Similar to other categories, price inflation has been most extreme in recent years, accounting for more than 80% of the diabetes category's 26.4% spending growth in 2014.

330. In fact, the diabetes category accounted for two-thirds of Express Scripts' Medicare traditional drug spending growth for the entire 2010-2014 period. As will be discussed in greater detail later, despite a wide array of interchangeable products, all drugs in all four of the major diabetes categories (DPP-4 inhibitors, SGLT-2 inhibitors, GLP-1 agonists and insulins) have exhibited severe and virtually uniform price inflation in recent years.

331. In the Medicare portion of its *Drug Trend Reports*, Express Scripts also provides some data on its top-ten spending individual products. After severe price inflation, in 2014, Sanofi's long-acting insulin, Lantus, became the top-spending drug in Express Scripts' Medicare business. See **Exhibit 30**. In 2013, Express Scripts' Lantus spending in Medicare Part D increased 26.5%, including a 21.1% contribution from price increases. The Lantus trends for 2014 are even more indicative of anti-competitive behavior. In 2014, Express Scripts' Medicare spending for Lantus increased 23.3%, despite an 8.4% decline in the product's usage. The

cost per patient for Lantus in Express Scripts' Medicare business increased by more than 50% over the past two years, despite a 4% decline in patient use over the period.

332. Because generic competition has not been a significant threat in specialty drug categories to date, the opportunities for severe price inflation are broader. Not surprisingly, the magnitude of specialty drug pricing fraud appears greatest in the largest categories that drive the majority of spending, namely multiple sclerosis (MS), anti-inflammatory drugs and oncology. These three major specialty categories account for more than 60% of specialty drug spending across the US.

333. As noted in the Relator's prior Qui Tam filings, the US multiple sclerosis category has exhibited the most uniform and severe anti-competitive price inflation since the 2006 start of Part D. Despite accelerating competition, all-available US MS drugs now cost in excess of $60,000 per patient, compared the $15,000 range just prior to the start of Part D. In its Medicare business, Express Scripts has reported an average 14% increase in MS patient drug cost per year between 2010 and 2014. See **Exhibit 31**. In the anti-inflammatory category, Express Script's reported an average 12% increase in annual Medicare cost-per-patient between 2010 and 2014, which accounted 65% of the category's growth. In Express Script's Medicare business, average oncology drug price inflation of 14% a year accounted for 53% of the categories growth between 2010 and 2014. However, the Relator's complaint focuses on the CML cancer sub-segment where price inflation has been more severe.

334. Within Express Scripts' Medicare business, MS, anti-inflammatory and oncology drugs comprised seven of the top ten spending drugs in 2014, with the remaining three being recently-approved hepatitis C therapies. The reported volume and pricing trends for many of these products are highly-indicative of anti-competitive behavior in Part D. See **Exhibit 32**. For AbbVie's Humira, Express Scripts reported a 47% increase in cost per patient since 2010, nearly double utilization trends. The AbbVie trends have even become more concerning in recent years. In 2013 and 2104, price increases have accounted for 70-80% of the products 17-24% annual spending growth. For Amgen's Enbrel, price increases have accounted for 96% of the product's

spending growth since 2010. Overall, the average cost per patient for Enbrel increased by 43% since 2010, with only a 2% increase in volume. Just since the start of 2013, the cost per patient for Enbrel rose 30% while utilization declined -3.7%. The already severe price for Novartis' oral CML cancer therapy, Gleevec, increased an average of 16% per year since 2010 while volume has grown only 3.9% on average. Again, the trends are most severe in recent years. Just since the start of 2013, Gleevec's price has increased by 33.5%, while utilization rose only 6% in the face of stiff competition.

335. Express Scripts' category spending forecasts for the next three years in its commercial insurance segment also suggest ongoing BFSF-related pricing fraud in Part D. After 18% diabetes commercial drug spending growth in 2014 (90% due to price increases), Express Scripts forecasts a similar 18% increase in each of next three years. Regarding the diabetes market, Express Scripts states in its 2014 *Drug Trend Report*: *"Although only slight year-over-year increases in utilization are projected, substantial continued increases in unit cost are likely to come from brand innovation, steady inflation of branded drugs and switches from older generic monotherapies to newer combination products."* After 24% anti-inflammatory specialty drug spending growth in 2014 (65% due to price increases), Express Scripts forecasts 21-22% spending growth each of the next three years. In the same report, Express Scripts states: *"The basis for the per-member-per-year (PMPY) trend forecast for medications to treat inflammatory conditions. Is sustained increases in both utilization and cost."* After 21% specialty oncology spending growth in 2014 (56% due to increased drug costs), Express Scripts forecasts 20-22% spending growth each of the next three years. In the same report, Express Scripts states: *"The year-over-year trend forecast for oncology medications is based upon continuations of brand inflation and brand-drug innovation."*

336. Overall, after 32% commercial specialty drug spending growth in 2014 (82% due to increased drug costs), Express Scripts forecasts 22-23% annual growth each of the next three years. These forecasts indicate severe ongoing BFSF-related Part D pricing fraud at Express Scripts, with carryover to the private insurance segment.

CMS PART D SPENDING TRENDS INDICATIVE OF ACCELERATING BFSF FRAUD

337. Overall Medicare Part D spending trends have been relatively modest in the first decade of the program, averaging a 3-4% annual increase. In fact, until recently Medicare Part D spending has been *"under-budget"* relative to initial Congressional Budget Office (CBO) forecasts for the program back in 2003. However, independent research clearly indicates that the modest spending trends in Medicare Part D during its first decade resulted primarily from systemic trends not particular to the program itself. First, Part D and private insurance market spending were both impacted by wide-ranging patent expirations that were not anticipated in the initial CBO Part D forecast. The CBO used an average 9% spending growth rate estimate in its 10-year Part D projection. In reality, spending growth across the US drug market, not just in Part D, average only 3% per year due to numerous patent expirations. Second, numerous independent analyses verify that Part D enrollment in the program's early years was far below the CBO's targets. *Kaiser Family Foundation, Issue Brief, May 2012*. Regardless, the pharmaceutical and PBM industries, as well as CMS itself, to this day cite the initial inaccurate 2003 CBO forecast as evidence of private industry's ability to effectively control Part D spending.

338. In April 2015, OIG released its second analysis (a follow-up to a similar August 2011 report) documenting the vastly greater manufacturer rebates in Medicaid compared to Medicare Part D, entirely attributable to severe drug price inflation. In a letter commenting on the report, the former Administrator of CMS, Marilyn Tavenner, stated: *"The Part D program has significantly outperformed cost estimates, resulting in lower than expected premium levels since the inception of the program". OIE-03-10-00650, Medicaid Rebates For Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. Higher Rebates for Brand-Name Drugs Result in Lower Costs for Medicaid Compared to Medicaid Part D, April 2015.*

339. More recently, on August 14, 2105, the Pharmaceutical trade organization, PhRMA (Pharmaceutical Research and Manufacturers of America) released a brief article entitled: *"The Truth about Negotiation in*

Medicare Part D". In the article, the PhRMA states: *"Claims that there are no price negotiations currently taking place in Medicare Part D are false. Large powerful purchasers – who represent as many as 63 million to 125 million covered lives (more than just Part D patients) – negotiate directly with prescription drug manufacturers to secure discounts and rebates under the program…the Medicare Trustees report that brand rebates are substantial. According to the Trustees, average rebate levels have exceeded projections and increased each year of the program…The success of Medicare Part D – and the program's competitive structure that allows for private negotiations and substantial rebates – is evident. Total program costs are 45% - or $349 billion – lower than CBO's initial 10-year projections. Part D continues to offer older Americans and people living with disabilities access to affordable prescription drug coverage, stable average monthly premiums and a program where 90% of beneficiaries are satisfied with the coverage.*

340. Unfortunately, the Relator's investigation has determined that the misleading overall Part D spending trends have also provided *"cover"* for massive anti-competitive pricing activity in the program. In reality, Part D has endured massive price inflation for the shrinking pool of remaining outpatient brand drugs, which now account for less 20% of overall prescription volume in the program (down from about 45% at the start of Part D.) The cost per Part D beneficiary for a wide array of remaining brand drugs has increased by an astounding three to six-fold from the 2006 start of the program to the present time. While severe brand price inflation has been nearly ubiquitous in Part D, some of the most extreme price increases have occurred for already high-priced specialty drugs, such as treatments for multiple sclerosis, rheumatoid arthritis and cancer.

341. CMS' own data illustrates the diverging impact of patent expirations and severe brand price inflation during the first decade of Medicare Part D. First, the Part D *"Regular Subsidy"* cost-per-beneficiary declined by 25% between 2006 and 2013 due to a wide array of patent expirations. See **Exhibit 33**. The *"Regular Subsidy"* represents the annual drug cost for the average, relatively healthy Medicare Part D beneficiary. These healthier beneficiaries typically do not require treatment with extreme-priced specialty drugs or a wide variety of brand drugs.

342. Unfortunately, the generic cost savings was more than offset by the severe price inflation of the dwindling number of remaining brand drugs, especially specialty drugs, since the start of the Part D program. This vast inflation is reflected in the increase in *"Low Income Subsidy (LIS)"* payments for fully taxpayer-fund, economically-disadvantaged, elderly and disabled Part D beneficiaries.

343. However, the greatest indication of this pricing fraud is reflected in the surging number of non-LIS Part D beneficiaries that are exceeding the modest annual *"Catastrophic"* spending thresholds at an accelerating pace each year. Since the start of Part D, annual "*Reinsurance Subsidy"* payments, which are 80% covered by CMS and taxpayers, have nearly quintupled from $6.0 billion in 2006 to $27.8 billion in 2014. See **Exhibit 33**.

344. With the wave of traditional drug patent expirations now moderating, the impact of severe brand price inflation, especially regarding specialty drugs, is now greatly impacting overall US pharmaceutical spending trends and the Part D program. Recently, all major constituents, including the largest PBM Defendants (Express Scripts and CVS Caremark) , IMS and CMS reported a similar acceleration in annual US drug spending growth from 3-4% in 2013 to 12-14% for 2014.

345. Specific to Part D, the Medicare Trustees released their 2015 Annual Report on July 22, 2015. The data is highly-indicative of the accelerating fraud outlined in this complaint. The Trustees reported that the Medicare Part D spending trend tripled from a 4% increase in 2013 to a 12% increase in 2014. Overall Part D program spending increased from $69.3 billion in 2013 to $77.7 billion in 2014. However, the subsidy components of this growth are the most troubling aspect. See **Exhibit 33**. The Trustees reported an 8% decrease in *"Direct Subsidy"* payments from $20.3 billion in 2013 to $18.7 billion in 2014. The Trustees reported a 5% increase in *"Low Income Subsidy"* payments from $23.2 billion in 2013 to $24.3 billion in 2014.

346. The overwhelming driver of increased Part D spending was a staggering 44% increase in *"Reinsurance Subsidy"* payments from $19.2 billion in 2013 to $27.8 billion in 2014. In a single year, the *"Reinsurance Subsidy"* share of the program's costs rose from 26% in 2013 to 33% in 2014. While the launch of hepatitis C drugs had significant impact in 2014, broad-based BFSF-related pricing fraud has been the primary cause.

347. Of note, despite the surge in spending, the Trustees disclosed only a slight increase in the percentage of manufacturer rebates, from 12.9% of total program spending in 2013 to an estimated 14.4% in 2014. Following the 2014 surge in Part D spending, the Trustees not surprisingly now forecast an acceleration in program cost trends due to *"an expected slowing of the trend toward greater generic usage and a continuing increase in the use and price of specialty drugs." 2015 Annual Report of the Boards of Trustees, released July 22, 2015.*

FIRST-HAND EVIDENCE FROM OCTOBER 2013 FMV OF BFSF CONFERENCE

348. Although the Relator previously uncovered all aspects of the fraud via independent investigation, definitive confirmation of the scheme came from his attendance at a conference specifically focused on the topic at the center of this Qui Tam case. On October 7-8, 2013 in Philadelphia, PA, the Relator attended a two-day conference sponsored by CBI, entitled, *"Fair Market Value of Bona Fide Service Fees"*. CBI is a subsidiary of Advanstar, which describes itself as *"the leading provider of market-driven, unbiased conferences for the pharmaceutical, biotechnology, medical device and healthcare industries."*

349. In his welcoming remarks, Chairman of the conference, Tom Evegan, the Senior Director of Commercial Contracting from Compliance Implementation Services (CIS), a leading government compliance consulting firm serving drug manufacturers, indicated the unique nature of the event. Mr. Evegan stated that the event represented the *"first ever"* conference specifically focused on FMV of BFSFs. CBI has not sponsored another conference specifically on the topic since the inaugural event.

350. The FMV of BFSF conference was primarily attended by senior staff from biopharmaceutical manufacturers responsible for federal program compliance, as well as representatives from leading consulting and law firms that advise industry regarding BFSFs and FMV. In addition, executives from several leading PBMs and specialty pharmacies were in attendance. Of particular note was the absence of CMS or any other government agencies at the conference.

351. The Relator has assembled contact information for the majority of presenters and attendees in **Exhibit 34.** This participation list is based upon the public agenda, as well as a private poster on display at conference. The list may not be accurate for late registrants or cancellations.

352. Key senior legal staff from Manufacturer Defendants were in attendance, including Pfizer (marketer of Lyrica, Viagra, Celebrex, Premarin, Chantix and Relpax), Sanofi (marketer of Lantus and Apidra), Amgen (marketer of Enbrel), AbbVie (marketer of Humira), Bristol-Myers Squibb (marketer of Sprycel) and Johnson and Johnson (US marketer of Simponi). In addition, the conference was attended by key staff from PBM Defendants and related companies, including Express Scripts and Diplomat Specialty Pharmacy. The meeting was also attended by representatives from other leading drug manufacturers, including Glaxo, Astellas, Gilead, Mylan and Otsuka.

353. The legal and consulting firms in attendance, who gave most of the presentations and led discussions, are among the largest and most influential firms with specific BFSF and FMV healthcare practices. A review of corporate websites indicates that these legal and consulting firms advise the majority of top pharmaceutical and biotechnology companies regarding compliance with government regulations. Other than CIS, attendees from the consulting arena included representatives from Huron Consulting and Navigant Consulting. On the legal front, attendees included representatives from King & Spalding, Reed Smith, Hogan Lovells and Sidley Austin. Of note, representatives from these consulting and legal firms have been mainstay presenters at virtually every conference regarding government drug pricing and compliance in recent years.

354. At the conference, the Relator listened to extensive industry testimony which fully corroborated all of the allegations of the fraudulent BFSF practices outlined in this complaint. Throughout the two-day conference, the Relator noted considerable tension and concern regarding industry's escalating legal risk exposure to BFSF fraud.

355. All key components of the alleged fraud were verified via presentations, candid discussions and direct quotes at the conference, namely:

i. *"Bona Fide Service Fees"*, rather than manufacturer rebates/discounts, have become the primary vehicle for manufacturer compensation of PBMs/specialty pharmacies in the Medicare Part D program;

ii. The majority of *"services"* provided by service vendors (including PBMs/specialty pharmacies in the Medicare Part D) should be valued via the *"Cost Approach"* to FMV assessment, including for high-cost specialty therapies;

iii. In practice, the standard contract terms between drug manufacturers and service vendors utilize *"percent of revenue"* terms, without adjustment for price increases, despite concerns about increased fraud risk.

iv. *"Percent of revenue"* service contract adjustments for significant price increases (to maintain an appropriate FMV range) are rarely being done in the marketplace, primarily due to the considerable negotiating leverage of large service vendors.

356. In just the first few minutes of his opening statements at the conference, Tom Evegan of CIS stated that *"fees were the key to government pricing"* and the majority of compensation to service providers from manufacturers had *"shifted from rebates to fees"*. The central role of BFSFs for PBM compensation was also verified by Mark Dewyngaert, a leading FMV expert from Huron Consulting. During his presentation on the second day, Mr. Dewyngaert stated that *"service fee agreements"* accounted for a *"substantial pool of money"* and were the *"main source of income"*.

357. Throughout the two-day conference, the leading industry and external FMV experts repeatedly highlighted the escalating fraud risk associated with the standard manufacturer/PBM *"percent of revenue"* contracts for products with significant price increases.

358. All the key issues surrounding this issue were covered in considerable detail by the very first presenter of the conference, John Shakow of the law firm King & Spalding. Mr. Shakow disclosed that he is a defense lawyer in the active Streck case regarding service fees in the Medicaid program. After providing some background on the history of BFSFs and potential legal risks, Mr. Shakow stated that he was *"not a fan of the market approach"* and that manufacturers need to *"consider whether percent of sales can be consistent with FMV as prices rise"*. He stated that it was *"a lot easier to have a fixed fee per unit of service"*, which would make him *"less worried regarding the impact of price increases"*.

359. Mr. Shakow went on to say that *"CMS has never said explicitly that percent of sales fees were not excludable"* (i.e., from government price calculations), but may be *"closer"* to doing so since these arrangements *"may bear no relation to the value of service unless (the service is) price-based"*. He expected that these *"percent of revenue*" deals will be *"challenged in the future"*.

360. Mr. Shakow also emphasized that the manufacturer's handling of fees must be able to "*withstand review/auditing by an independent party, which can determine the same FMV*", as well as *"justify the FMV to an outside party brought in by the government"*. Reflecting on the Streck investigation, he stated that the government will *"look beyond the agreement and evaluate the true nature of the fees, via emails, communications, interviews and sworn testimony"* in its search for *"intent"*.

361. Throughout the conference, numerous constituents emphasized the need to document and verify fees with vendors for appropriateness and FMV. Numerous experts emphasized the need for manufacturers to insist on *"audit rights"* in their service contracts, while also admitting little success with these requests.

362. In their presentation, Isabel P. Dunst, a partner at Hogan Lovells and Julie DeLong, the Director of Valuation and Financial Risk Management at Navigant Consulting, offered somewhat contrasting views regarding valuation methodologies. Ms. Dunst stated that she *"did not recommend percent of sales"* contracts to her manufacturer clients, while Ms. DeLong indicated more flexibility. Ms. DeLong stated that she *"can value anything"* and was comfortable *"translating per unit fees to percentage of revenue"*. Ms. DeLong elaborated, stating that *"some want to be paid in different ways"* and that she could *"translate FMV into a dollar amount per month or year, as well as a percent of revenues"*. Around the time of this discussion, Ms. Dunst stated that she hoped *"the conference was not being recorded"*.

363. Ms. DeLong also stated that the FMV was a *"snapshot in time"* and "*percent of WAC"* deals had greater risk with fast-rising prices. An audience member then asked about the proper FMV handling of fees for a $100 versus a $1,000 bottle with the same number of pills. Ms. Dunst, of Hogan and Lovells, did not provide a direct reply to this query, instead saying that a *"real problem was developing with percent of revenue"* contracts. The Relator views this commentary as particularly relevant for fast-inflating, extreme-priced oral specialty drugs.

364. Numerous presenters stated the *"Cost Approach"* is the most legally-justifiable FMV methodology for the vast majority of services provided for manufacturers by service vendors. In his discussion of contracting processes on the second day of the conference, John Moose of Huron Consulting stated that the *"business plan"* of the manufacturer/Service Vendor contract must recognize that *"most of the value of services comes from the connection with the patient"* and that a *"dollar amount per activity is the easiest to justify"*.

365. The *"Cost Approach"* to FMV was discussed in detail by two Johnson & Johnson government contracting executives, Michael Hepburn and Doris Chern, on the first day of the conference. Consistent with the Relator's analysis, the standard *"Cost Approach"* typically utilizes a *"rate grid"*, using a staff wage rate and time estimate to calculate FMV for a particular service.

366. Julie DeLong from Navigant Consulting and Isabel P. Dunst from Hogan Lovells also discussed the topic of FMV approaches to specific services provided by specialty pharmacies. Ms. Dunst stated that *she "does not view the specialty channel any differently from other channels"* regarding the handling of fees and FMV. The presenters did state that separating *"core"* and *"non-core"* services for specialty pharmacies, compared to traditional distribution channels, can be difficult for manufacturers. If a particular service is *"core"* to the business model of the specialty pharmacy and *"they are already doing it"*, the manufacturer "*should not be paying for it"*. The slide presentation included a list of the typical specialty pharmacy services, which are routinely offered by the PBM Defendants for specialty drug categories, namely processing/shipping prescriptions, patient benefits verification, refill reminders, customer service numbers, inventory and sales reports, patient adherence calls and patient counseling.

367. Ms. Dunst and Ms. DeLong indicated that virtually all the specialty pharmacy services are patient/unit based and should be valued using the *"Cost Approach"* to FMV determination. This expert commentary is consistent with the Relator's contention that the vast majority of BFSFs for specialty drugs should closely correlate with patient utilization.

368. Despite the uniform recommendation of the *"Cost Approach"* for FMV assessment, conference participants repeatedly admitted that this methodology is rarely used in practice. A definitive moment in the two-day conference came during the final presentation of the first day given by Jim Abrams, the Director of Government Pricing and Reporting at Mylan Pharmaceuticals. Mr. Abrams took a simple poll of the audience. He asked attendees to raise their hands *"if they were using a rigorous cost plus approach to qualify fees"* at the present time. Consistent with the Relator's investigation, only one person (a consultant), among the 40-45 conference attendees, raised his hand.

369. In his presentation, John Moose of Huron Consulting discussed the need for contract adjustments for both increasing drug prices, as well as for changes in service volume. He stated that unless manufacturers put *"adjustments in contracts for price changes"*, they *"run the risk of paying too much"*. He stated that

manufacturers need to *"refresh"* FMV based on a variety of factors, including price inflation, changes in service volume (pertinent for Manufacturer Defendant drugs in declining use), changes in service definition and the need for additional services. In the final presentation of the conference, Chris Jackson, the Corporate Attorney for Otsuka America Pharmaceuticals, reinforced the need for contract adjustments for price increases. He stated that *"multi-year deals based on the percent of WAC"* must be *"refreshed"*.

370. Despite his expert recommendation, Mr. Moose admitted that to date *"he has not done any refreshes for service contracts"*. As such, standard *"percent of revenue"* service contracts are rarely being adjusted for price increases in order to maintain appropriate FMV. In her conference presentation, Stephanie Gilson, the Chief Counsel of Defendant Johnson & Johnson, admitted that *"percent of WAC (Wholesale Acquisition Cost), deals are often not updated by manufacturers"*.

371. Lack of service vendor transparency was reinforced during the final presentation of the first day by Jim Abrams of Mylan. After stating that *"customer (i.e., service vendors, including PBMs) engagement was very little"*, Mr. Abrams again polled the audience of manufacturers and consulting/legal advisors, asking for an indication of who had *"engaged vendors to assess fee structure"*. Out of the 40-45 attendees, only 2 raised their hands. The Chairperson of the conference, Tom Evegan of CIS then commented that *"very few vendors were willing to provide the data"* and were *"worried"* about doing so. Mr. Evegan expressed concern since *"manufacturers were looking for documentation since manufacturers were responsible if ever challenged"*. Finally, Mr. Shakow of King and Spalding stated that *"up to a few years ago few contracts gave specifics regarding fees"* and this *"could be trouble"*.

372. John Moose from Huron Consulting said that he expected the recent favorable trend in contract terms for larger service vendors to *"accelerate"* even further in the future due to their rising negotiating leverage with manufacturers.

373. Further commentary indicated the central role of the PBM Defendants in *"percent of revenue"* service contracts and BFSF fraud. Mr. Shakow stated that shifting away from *"percent of revenue"* service contracts was difficult because *"wholesalers and distributors all want percent of revenue deals"* and change required *"getting partners to agree"*. In his presentation, Mark Dewyngaert, of Huron Consulting, stated that *"often partners (i.e. service vendors) will not allow cost plus"* fee determinations. Johnson and Johnson Assistant General Counsel, Stephanie Gilson, Defendant Johnson & Johnson's Assistant General Counsel, stated that they were *"trying to work with intermediaries"* in order to decrease their reliance on *"percent of WAC"* contracts, but were getting *"strong pushback from service providers"*. She suggested that to change these business practices may require either a *"manufacturer industry initiative"* or a *"CMS mandate"*.

374. Expert commentary from the conference also indicated that the federal government has been struggling to address industry practices. Ms. Gilson of Johnson and Johnson, stated that the Office of the Inspector General (OIG) *"has been looking at AMP practices"*, but *"really had little knowledge"* and the *"learning curve takes time"*. She further stated that the OIG auditors had only just *"engaged"* with J&J directly on this issue recently in the *"second quarter of 2013"*. An attendee agreed that the OIG was *"behind industry"* and asked when the government would be *"dangerous enough to understand how industry works"*. Ms. Gilson responded that she thought *"CMS was getting burned out because a lot of stakeholders were in their ear"*.

RELATOR'S PATH TO FRAUD DISCOVERY

375. The extreme disparity between price and volume trends for many older traditional and specialty drugs, both in Part D and the private insurance sector, was the starting point for the Relator's extensive investigation. Based upon his 25-year history as both a physician and a dedicated healthcare analyst/portfolio manager, the Relator quickly realized that collusive behavior between drug manufacturers and PBMs was at the center of these troubling trends. From his analyses stemming back to the early 1990's, he knew that PBMs were highly capable of extracting significant discounts from manufacturers for favorable formulary placement of brand

drugs competing in crowded therapeutic categories. In fact, this strategy, called *"therapeutic substitution"* has been a cornerstone of the PBM industry for decades.

376. Furthermore, with subsequent extreme horizontal and vertical integration of the PBM and specialty pharmacy industries, the Relator knew that PBM industry negotiating leverage with drug manufacturers had increased significantly over the past several decades. If anything, PBMs should now be far more successful in both garnering discounts and preventing price inflation in crowded brand drug therapeutic categories, if their interests were properly aligned with their clients.

377. Despite clear evidence of severe anti-competitive drug pricing activity, the Relator found public commentary from industry to be sparse and disingenuous. Drug manufacturers almost uniformly provide minimal or rote explanations for the severe price increases. Common manufacturer statements include: "*we price our products competitively*", "*we price our products commensurate with their value*" and "*premium prices are required to fund research and development*".

378. Given his extensive knowledge of PBM cost-savings strategies, the Relator found PBM industry public commentary to be particularly deceitful, especially regarding specialty drugs. In their public disclosures, PBM executives routinely claim that their financial interests are always aligned with their payer clients. Regarding fast-inflating specialty drugs, PBM executives routinely state that the drug prices are "*set solely by manufacturers*" and that the "*complexity*" of these drugs (and the medical conditions they target) have largely prevented aggressive cost management techniques.

379. As extreme-priced specialty drugs and price increases have attracted greater attention, the PBM Defendants have aggressively positioned themselves as adversaries with their collusive manufacturer partners, claiming to be a key part of the solution to uncontrollable drug US drug prices. In the Relator's view, the plethora of misleading and deceitful information arising from the Defendant parties represents a concerted and intentional effort to deflect attention from their mutually-coordinated fraud.

380. As a physician and long-standing healthcare analyst, the Relator knew full well that mature, crowded specialty brand drug categories (such as multiple sclerosis, rheumatoid arthritis and segments of cancer) offered the same, if not greater, "t*herapeutic substitution*" savings opportunities compared with many traditional brand drug categories. Furthermore, in many instances, the designation as a "*specialty drug*" in a PBM formulary is solely determined by a product's high price (as is the case in Part D), not the complexity of either the therapy or the condition it treats.

381. Furthermore, many of the new high-priced so-called *"specialty drugs"* reaching the market are oral drug that typically require far less *"support services"* compared to older injectable *"specialty drugs"*. For instance, oral drugs obviously do not typically require special handling (e.g., refrigeration, overnight shipping, etc.) or special patient training (e.g. injection training) that is required for many older injectable specialty drugs. In the Relator's view, the PBMs were simply taking advantage of less-informed payers, while using self-propagated confusion around *"specialty drugs"* to garner substantial financial gains in a collusive pricing scheme with drug manufacturers.

382. Factors specific to Medicare Part D heightened the Relator's focus regarding the program's influence on accelerating drug prices. First, from a review of pricing trends for a wide array of brand drugs (especially multiple sclerosis drugs at the start of his investigation), the Relator noted a close association between the onset of accelerating US price increases and the start of Medicare Part D. Most of the implicated products exhibited accelerating price increases starting with the 2006 enactment of the program, while a smaller proportion even began rising sooner after the 2003 passage of the legislation. Second, the Relator realized that the first-ever elderly federal drug benefit was essential for deflecting political and public scrutiny from massive drug price increases. Prior to Part D, extreme price increases on outpatient drugs would have quickly led to broad outrage due to the severe financial burden placed on a large number of high drug-consuming elderly Americans without insurance coverage.

383. Several additional discoveries early on in his investigations led the Relator to target Medicare Part D as the source of this systemic price collusion scheme between drug manufacturers and PBMs. First, from reviewing government data, the Relator discovered that, contrary to legislative intent, manufacturer rebates for brand drugs in Part D were very modest each year of the program despite the massive brand drug price inflation. *Annual Medicare Trust Reports.* From this data, the Relator concluded that the vast majority of financial benefit from massive brand price increases in Part D has accrued to drug manufacturers.

384. Second, and most important in directing his investigation, the Relator noted, also contrary to legislative intent, that PBMs were *"retaining"* minimal rebates in the Medicare Part D program. According to Office of Inspector General (OIG) report (*OEI-02-08-0050, March 2011*), PBMs retained less than 1% or only $24 million of the $6.5 billion in total Part D rebates reported to CMS in plan sponsor *"Direct and Indirect Remuneration"* (DIR) reports for the plan year 2008.

385. To date, the March 2011 OIG report remains the only public disclosure regarding PBM *"retained rebates"* in Part D in the 10 years since the program began. This confusing finding posed the obvious question to the Relator: If the PBMs were not being compensated in Part D via "*retained*" manufacturer rebates as was expected by legislators and CMS, how were they getting paid? Given rising leverage of the PBM industry, the Relator knew that the dominant PBM Defendants would not allow severe brand price inflation in crowded, highly-competitive brand drug therapeutic categories, both traditional and specialty in nature, without receiving significant associated compensation from drug manufacturers.

386. Confused by this OIG disclosure, the Relator began an extensive search to uncover alternate methods of PBM compensation in the Part D program. The Relator's eureka moment came several months later in the late spring of 2013 when he came across a February 15, 2013 article in an industry trade journal, *Specialty Pharmacy Times*. The article, entitled *"Why We Care about Bona Fide Service Fees?"*, was written by Chris Coburn, the Senior Vice President of Government Programs at Compliance Implementation Services (CIS). CIS is leading consulting firm for pharmaceutical manufacturers. This article was the first time the Relator

became aware of the term *"bona fide service fees" (BFSFs)*. In the article, Mr. Coburn discussed the quandary manufacturers faced in properly valuing BFSFs. In the article, Mr. Coburn stated: *"The proposed rule for AMP (average manufacturer price, a reference price in Medicaid) published by CMS at the end of January states that they will not define FMV ("fair market value") and would put the burden on the manufacturer. This is difficult, as most of the service-type fees paid are based upon a percentage of sales."*

387. This single article set off a cascade of research and investigation by the Relator regarding BFSFs, FMV and their relevance to the Medicare Part D program. Over the next several months, the Relator uncovered all key aspects of the BFSF fraud. He determined that drug manufactures and the large PBM Defendants, who control the majority of Part D plans and enrollment, had utilized the lax regulatory handling/oversight of BFSFs in a collusive scheme of staggering magnitude. Together the collusive partners used the scheme to vastly inflate drug prices in Medicare Part D. In the scheme, the manufacturers reap the majority of the gains via fraudulent revenue increases from vast anti-competitive drug price increases in Part D. In turn, the PBMs gain fraudulent revenues via secretive rising BFSFs from drug manufacturers, contractual-linked to the massive price increases.

RELEVANCE OF THE AWP LIGATION AND THE MMA ACT

388. The Relator has determined that the BFSF fraud at the center of this systemic Part D scheme was promulgated by a dramatic shift in financial incentives imposed on industry by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 *("MMA")*. MMA both enacted the outpatient Medicare Part D program and significantly altered drug reimbursement for provider-administered drugs in the Part B program. Most importantly, Medicare Part D greatly altered the handling and disclosure requirements for drug *"spreads"* and *"manufacturer rebates"*, prior key revenue/profit centers for the PBM industry.

389. Prior to MMA, commonly in practice, drug service providers, including PBMs, could receive government reimbursement at high *"list"* prices (typically Average Wholesale Price ("AWP")), keeping the *"spread"*

differential between their lower acquisition costs. For provider-infused drugs, in both Medicare Part B and the private sector, the *"spread"* is the difference between the reimbursement obtained by the provider (a physician most commonly) and the amount the physician pays for the drug. Regarding outpatient drugs, industry experts most commonly refer to *"spread"* as the difference between the amount a provider (typically a PBM or wholesaler) pays a dispensing pharmacy and the amount the provider charges its payer client. In the private sector, payer clients are typically health plans, unions and self-insured employers.

390. PBM-negotiated *"manufacturer rebates"* are another type of "*spread"*. Regarding rebates, the *"spread"* is the difference between the amount the PBM pays the dispensing pharmacy and the PBM's acquisition cost from the drug manufacturer.

391. Prior to MMA and Medicare Part D, none of these *"spreads"*, including those regarding *"manufacturer rebates",* were in the public domain or routinely disclosed by PBMs to payer clients.

392. As was widely-known, prior to Medicare Part D, a primary profitability driver for PBMs was the portion of *"manufacturer rebates"* they *"retained"*, rather than passed along to private payer clients. As per the SEC 10-K filing of Medco Health, the largest PBM at the time, *"retained"* manufacturer rebates accounted for more than 100% of the company's profits in 2003, the year Part D was passed into law.

393. Allegations of *"spread"* abuse fueled the wide-ranging Average Wholesale Price ("AWP") Litigation, which began in 1995 with the first Qui Tam filing by Florida-based Ven-A-Care (*United States ex. Rel. Ven-A-Care of the Florida Keys, Inc. v. Bristol Myers Squibb, et. al., CA No. 95-1354*). To date, drug manufacturers and drug wholesalers have paid more than $1.5 billion to settle AWP allegations, with numerous cases still ongoing in the consolidated Massachusetts Federal District Court.

394. While the AWP Litigation primarily targeted provider-administered drugs in Medicare Part B (with later cases in the private sector), the legal activity led to increased disclosure and limitations on future *"spread"*

opportunities in MMA for both Medicare Part B and the new Part D program. In Part B, MMA shifted reimbursement for provider-administered drugs from one based upon unreliable, and often inflated, AWP prices to one based upon ASP *("Average Sales Price").* The providers would be reimbursed at 6% above the ASP, a closer estimate of the provider's actual acquisition cost for the drug.

395. Given the historic role of *"manufacturer rebates"* in the private sector, the Part D laws and regulations were written assuming similar dynamics would prevail in the new outpatient drug program. Congress and CMS assumed that PBM financial interests would be fully aligned with CMS and Part D beneficiaries in an effort to lower drug costs. Congress and CMS expected PBMs to negotiate with drug manufacturers for significant brand drug rebates/discounts, particularly for drugs in crowded brand drug therapeutic categories. Similar to the private sector, drug manufacturers would provide these discount in highly-competitive brand drug categories in order to gain greater market share via favorable Part D formulary placement. These standard "t*herapeutic substitution*" formulary strategies had been effectively employed by PBMs in the private sector for at least 15 years prior to the start of Part D.

396. With a goal of increased transparency in the new government program, Part D regulations require a full reporting of all forms of discounts (including manufacturer rebates) negotiated by PBMs from manufacturers. In addition CMS requires the direct reporting to CMS of the portion of manufacturer discounts/rebates that are *"retained"* by PBMs. This information is provided to CMS in annual the *Direct and Indirect Remunerations* (DIR) Reports submitted by Part D plan sponsors.

397. The MMA also required disclosure of the *"pharmacy"* drug price and dispensing fees in PDE reports, thus largely eliminated brand drug *"spread"* profit opportunities for PBMs between payers, pharmacies and CMS in Part D. Notably, Part D dispensing fees paid to retail pharmacies are quite modest. According to a January 2008 OIG report, Part D dispensing fees paid to local and community pharmacies averaged $2.27 per prescription, about $2 lower than average dispensing fees in the Medicaid program. *A-06-07-00107, January 2008.* For specialty drugs, dispensing fees are often waved by the PBM Defendants in order to

incentivize use of their wholly-owned or closely affiliated mail order pharmacies and their *"preferred"* pharmacy networks. The handling of *"spreads"* between the various wholly-owned and/or closely-related functional entities in Part D for the PBM Defendants, namely plan sponsor, PBM and specialty pharmacy, could be a key area of fraud investigation in this Qui Tam case.

398. While Part D opened up a significant new elderly and disabled target population to drug markets, the transparent handling of rebates/discounts posed a conundrum to the business practices of both drug manufacturers and PBMs. In reality, prior to Part D, the PBM industry was dependent upon rebates *"retained"* from drug manufacturers for its profitability. Similar business practices in Part D, given its full disclosure requirements, would expose the PBM Defendants' financial dependence on drug manufacturers, thereby attracting more scrutiny to an already highly controversial industry.

399. Given the vast disparity in financial resources of the high-margin pharmaceutical industry relative to the lower-margin PBM sector, both Defendant parties were highly incented to cooperate, if possible, in the more transparent Part D program. The aggressive pursuit of brand drug rebates by PBMs in Part D would be detrimental to the financial prospects for drug manufacturers. However, the PBMs also faced diminishing prospects in the new program. Whereas aggressive brand rebates would benefit PBMs in the near-term, the resulting lower *"negotiated prices"* would decrease future PBM rebate and profit opportunities in subsequent Part D program years.

400. To further complicate matters, Part D began when both drug manufacturers and PBMs faced major threats to their viability. Most importantly, manufacturers faced an unprecedented number of major patent expirations in the early-to-mid 2000s. These same manufacturers became increasingly dependent on a smaller number of remaining brand drugs, many of which were maturing and facing rising competition. While PBMs would undoubtedly benefit from rising generic use, the absolute dollars garnered as drug prices plummeted following patent expiry (even with reportedly higher PBM percentage margins for generic drugs) paled relative to prior *"retained"* brand manufacturer rebates on premium-priced brand drugs.

401. In the face of these regulatory and business challenges, rather than following the intent of the Part D legislation, the Manufacturer and PBM Defendants entered into a collusive pricing scheme of unprecedented proportions based upon a stealth provision of Part D pertaining to *"bona fide service fees"* (BFSFs).

402. As noted previously, another central factor facilitating the fraud is the lack of functional restrictions within Part D. To this day, virtually all government communications/analyses discuss the Part D program as if the major functions (sponsor, PBM and specialty pharmacy) are provided by independent organizations. This regulatory shortcoming has contributed to massive horizontal and vertical integration of the PBM and specialty pharmacy industries. The Relator believes this oversight has had a cataclysmic impact on the Part D program, contributing to extreme concentration, decreased transparency and severe anti-competitive pricing activity.

403. In conclusion, the Relator has come to realize that the BFSF allegations in this complaint are in many ways an extension of the *"spread"* abuse allegations that spurred the wide-ranging AWP litigation and resulting MMA Act. With the MMA legislation requiring full disclosure of spreads and rebates in Part D, BFSFs became the only major pathway for large *"non-transparent"* payments from drug manufacturers to PBMs in the program. Furthermore, with a wide swath of patent expirations, fraudulent BFSFs tied to massive price increases for the shrinking number of remaining brand products (both specialty and traditional) became the primary avenue for mutual growth for the co-dependent Manufacturer and PBM Defendants.

404. However, the magnitude of alleged BFSF fraud is many fold greater than with the AWP cases. First, the outpatient drug program is now more than three times larger than Part B, with a large proportion of Part D's growth attributable to systemic pricing fraud related to BFSFs. Second, in this BFSF case, all the financial benefit of the vast price inflation fraud has accrued directly to the Manufacturer and PBM Defendants. In contrast, in the alleged AWP spread abuse cases, the drug manufacturers often aggressively discounted drug acquisition costs to widen *"spreads"* and incentive use by providers. It was the providers (usually physicians), not the manufacturers, that pocketed the excess reimbursement based upon falsely-inflated AWP

prices. Physicians and other drug providers (including PBMs) have not been pursued as defendants in the AWP litigation.

405. Ironically, despite the extensive AWP litigation, fraudulent AWP pricing remains a key factor in BFSF pricing fraud in the Medicare Part D program.

LONG-ESTABLISHED *"THERAPEUTIC SUBSITUTION"* CAPABILITIES OF PBM DEFENDANTS

406. As a veteran Wall Street healthcare analyst who has followed PBMs closely for 25 years, the Relator has first-hand knowledge of the industry's long-standing *"therapeutic substitution*" capabilities.

407. In the early 1990's, Merck sold the leading brand cholesterol drugs, Mevacor and Zocor, which competed intensely with Bristol's Pravachol. In the hypertension market, the competition was even fiercer between Merck's ACE (Angiotensin Converting Enzyme) inhibitor franchise (Vasotec and Prinivil) and products from Bristol Myers, ICI, Ciba and Warner Lambert. Similar to current dynamics in numerous traditional and specialty categories, the various products in these cardiovascular therapeutic areas were quite similar in profile, with modest efficacy and safety differences.

408. Medco was the dominant PBM in the early 1990's, but controlled a very modest share of US drug spending. Despite its limited market share, Medco had a tremendous influence on these major cardiovascular therapeutic categories.

409. During this period, Medco excluded Merck's cardiovascular products from its formularies. As a pharmaceutical equity analyst at the time, the Relator tracked the significant impact of Medco's formulary exclusion on Merck's franchise using monthly IMS prescription data. Between November of 1992 and November of 1993, Merck's share of the ACE inhibitor fell 4.6% points, from 49.0% to 44.4%. With

somewhat less competition, Merck's share of the cholesterol market fell 1.7% in the year ending November 1993, from 49.3% to 47.6%. See **Exhibit 35**.

410. Strong validation of Medco's impact came in November 1993 when Merck acquired Medco. After the merger, Merck quickly began reversing its market share trends. Merck regained 1.5% and 1.0% of share in the ACE inhibitor and cholesterol markets, respectively, just 3-4 months after closure of the merger. See **Exhibit 35.** With preferred positions in Medco's retail and mail order networks, Merck went on to aggressively defend its core franchises for years to come. Facing similar threats to core brand therapeutic areas, Eli Lilly and SmithKline Beecham subsequently acquired the two other major PBMs of the time, PCS Health Systems and Diversified Pharmaceutical Services (DPS), in 1995.

411. At the present time, the current savings opportunity in numerous traditional brand and specialty drug categories would be vast if PBM Defendants' financial interests were aligned with their clients. In the early 1990s, Medco had a dramatic impact on the largest US drug companies and the largest drug categories when the PBM industry was a fraction of its current size. For reference, Medco generated revenues of approximately $3.0 billion in 1993, accounting for only about 5% of the $60 billion US pharmaceutical market at the time. In comparison, after massive growth and consolidation, Express Scripts and CVS Caremark, the two largest PBMs, had PBM revenues in the $95 billion and $75 billion range, respectively, in 2013. These two companies alone now account for about 60% of the overall US pharmaceutical market (and about 65% of Part D plans), with the entire PBM industry now managing about 82% of drug spending in the country. Normal competitive dynamics would suggest that PBM negotiating leverage should be far greater and more sophisticated at the present time compared to 20 years ago.

412. Similar to the early 1990's, the large US traditional brand and specialty drug categories are now crowded with therapies offering similar clinical profiles, most of which have now been available for many years. The multiple sclerosis specialty category now includes eight to nine injectable and oral therapies offering similar efficacy. The inflammatory specialty category has four anti-TNF drugs with similar clinical profiles. In the

diabetes space, numerous virtually identical oral and injectable therapies are now available in all four major brand drug segments. In the cancer area, three similar, first-line treatments for CML (chronic myeloid leukemia) are available in the US.

413. Despite the long-standing availability of numerous similar therapies, severe systemic and uniform price inflation has occurred in all these drug categories. The most severe examples of fraudulent pricing has occurred for products facing declining prescription trends. Notable examples include Biogen's Avonex in the multiple sclerosis category and Amgen's Enbrel in the inflammatory segment. Mutually-beneficial fraudulent BFSFs between the Defendant parties are the cause of these egregious pricing trends.

414. Since 2012, the two largest PBM Defendants, Express Scripts and CVS Caremark, have highlighted their efforts to control drug costs by excluding a number of brand drugs, including high-cost specialty therapies, from their National formularies. Express Scripts has publicly disclosed that a third of its client base fully incorporate its National formulary in their plans. Express Scripts has 66 products on its 2015 formulary exclusion list, up from 48 in 2014. CVS Caremark has 95 products on its 2015 exclusion list, up from 72 in 2014. *Drug Channels, Adam J. Fein, August 5, 2014.*

415. However the nature and financial impact of these recent PBM formulary exclusions is far different compared to the effective strategy employed by Medco against Merck in the early 1990s. Two decades ago, Medco excluded Merck's market-leading ACE inhibitor products and cholesterol products from its formularies. In November 1992, Merck's ACE franchise (Vasotec and Prinivil) and its cholesterol-lowering franchise (Mevacor and Zocor) accounted for 49% of US prescriptions in their respective categories. Companies with far smaller market share products were willing to provide significant discounts for access to this considerable market share. The formulary restriction of drugs with significant market share is essential to the success of PBM brand *"therapeutic substitution"* cost-savings programs.

416. In sharp contrast, at the present time, the vast majority of excluded products on both the Express Scripts and CVS Caremark formularies are minor products with low levels of sales and market share. Both PBMs have excluded few products in major therapeutic categories, and mostly only those with a minor market share which offer little opportunity for effective *"therapeutic substitution"* programs. For instance, in the large MS specialty category, despite a wide array of similar products, starting in 2014 Express Script only excluded Bayer's Betaseron, a product whose utilization was already plummeting due to severe competition from new products. Starting in 2015, CVS Caremark excluded Pfizer/Serono's Rebif, which has been eroding similar to Betaseron. Neither of these formulary decisions has any impact on the severe price inflation for Betaseron or other MS drugs.

417. In the large inflammatory category (e.g., rheumatoid arthritis), neither Express Scripts nor CVS Caremark has indicated any preference between the two dominant product, AbbVie's Humira and Amgen's Enbrel, which comprise 80% of the market. Express Scripts has excluded Cimzia and Simponi, with a combined market share of 8%. Caremark has not excluded any anti-TNF drugs from its national formulary. Again, these minor exclusions have had no apparent impact on the vast US price inflation of all four anti-TNF drugs in recent years.

418. In the diabetes category, both PBMs have excluded the same DPP-4 inhibitors with small market shares (Nesina, Onglyza, Oseni), while both placing Merck's dominant product, Junuvia (51% of the US DPP-4 market as of May 2015, as per IMS) in preferred position. Among insulins, for the last several years, CVS has excluded Eli Lilly products, while Express Scripts has made them preferred products. Both AWP and corporate-reported US sales indicate these formulary positions have had little impact on the uniform severe price inflation in the category and accelerating diabetes spending trends.

419. Despite recent escalating anti-pharmaceutical rhetoric from senior management, Express Scripts' recently-released 2016 exclusion list is actually less restrictive compared to the prior year. Despite the new availability of a generic version of market-leading Teva's Copaxone, Express has not excluded any MS drugs

in its 2016 formulary. In fact, Express Scripts added back Betaseron to its approved drug list. Express Scripts made no additional changes to its ant-TNF formulary and minimal changes regarding diabetes.

420. The only notable 2016 addition to CVS formulary was the exclusion three MS drugs for the first time, Biogen's Avonex/Pledigry franchise and Novartis' Extavia (identical to Bayer's Betaseron). As with Express Scripts, CVS made no effort to limit access to brand Copaxone, despite an available generic. While these first-time CVS exclusions offer cost-savings potential, they arrive after nearly a decade of relentless BFSF-driven severe price inflation in the MS category.

421. Despite unverifiable claims of large client savings from these formulary exclusions, overall the formulary exclusions since 2012 at these two dominant PBM Defendants (together more than 50% of both the PBM and specialty pharmacy industries) have had no detectable impact on the US drug price or spending trends, especially regarding specialty drugs. In fact, the Relator has documented that price increases have actually accelerated over the past several years. Furthermore, the recent overall spending and price inflation trends for all major traditional and specialty brand drug categories have been virtually identical for Express Scripts, CVS Caremark, the other PBM Defendants, as well as across the broader US pharmaceutical market.

422. Of course, there is also no way to independently verify the implementation of the Express Scripts and CVS Caremark formulary exclusions. Furthermore, neither PBM provides any information regarding financial arrangements with manufacturers pertaining to its formularies. As such, favorable service fees, rather than rebates/discounts that benefit clients, may often by the key factor driving formulary inclusion.

423. In the Relator's view, these PBM Defendant formulary disclosures are designed to maximize public relations impact rather than to drive actual savings for payer clients. Furthermore, the cooperation of the Defendant parties regarding drug coupons in the private sector and patient assistance programs in Part D prevents the enforcement of differential cost-sharing which is essential to effective formulary implementation.

424. In reality, the Manufacturer and PBM Defendants are seeking to maximize the prices, revenues and service fees for the majority of brand products, but especially the market leaders in the major US therapeutic categories. In announcing its 2016 formulary, Express Scripts stated that the goal of its negotiations is to target *"reasonable pricing, not exclusion"*. Unfortunately, in the fraudulent, systemic service fee model, *"reasonable pricing*" amounts to vast, uniform price inflation for the majority of US brand drugs, especially those in the major therapeutic categories.

DIRECT EVIDENCE OF PRICE UNIFORMITY/COLLUSION FROM MEDICARE PART D PLANS

425. In order to assess availability and price competition for major traditional and specialty brand drugs among Medicare Part D plans, in September 2013 the Relator performed an analysis using the eHealth www.planprescriber.com search engine, an aggregator of CMS-approved data. For three major zip codes in the New York City, Los Angeles and Minneapolis area, the availability and pricing of an array of leading brand drugs were reviewed for all available Medicare Part D plans in each respective regions. See **Exhibit 36**. The Relator specifically targeted brand drug therapeutic categories populated with numerous similar drug therapies, including multiple sclerosis, inflammatory conditions, and diabetes.

426. Notably, despite the potential for significant competitive and PBM formulary restrictions in these crowded therapeutic categories, virtually all major specialty and traditional brand drugs were available in all 80 Part D plans across the three geographic locations.

427. The search also found that prices for all the screened brand drugs were virtually identical across all plans and regions, indicating a near complete absence of Part D drug price competition in these therapeutic categories crowded with numerous similar drug choices.

428. For instance, as of September 2013, after years of near lock-step severe inflation, the Part D cost for Novartis' Gleevec was identical at $72,783 in all plans across all regions. In the inflammatory category, the

plan cost for AbbVie's Humira and Amgen's Enbrel were virtually identical in the $26,000 range in all plans. In the multiple sclerosis segment, the individual drug costs for Biogen's Avonex, Teva's Copaxone and Pfizer/Serono's Rebif were also identical in the $42-50,000 per year range in every Part D plan serving the New York, Los Angeles and Minneapolis metropolitan areas.

429. Uniform pricing was also noted in the diabetes category. The plan cost for the two leading injectable GLP-1 drugs, Novo Nordisk's Victoza and Astra Zeneca's Bydureon, were identical in the $4,000 range per patient in all plans across the three regions. In a traditional oral DPP-4 diabetes category, the Part D prices for the three available products, which have virtually identical clinical profiles, were the same in all plans in all three geographic regions. All three DPP-4 drugs, namely market-leading Januvia from Merck, as well as AstraZeneca's Onglyza and Boeringer Ingelheim's Tradjenta, cost $2,800 per year per patient in September 2013.

430. In order to gain a better understanding of local competitive dynamics, the Relator took a closer look at the Medicare Part D plans listed as available, as per the same website, in Los Angeles in September 2013. A Relator search of individual plan websites was then performed in order to verify Part D sponsors, as well as to determine the PBM responsible for administering the drug benefit for each plan.

431. In the Los Angeles area, 27 Part D plans were listed as available as of late September 2013. However, this large number misrepresented the true underlying competitive dynamics. These 27 plans only included 10 distinct plan sponsors in Los Angeles, with all the plan choices managed by only 6 PBMs. Furthermore, 44% of plans were managed by Express Scripts and 18% by CVS/Caremark, together accounting for nearly two-thirds of Part D offerings in the Los Angeles area. See **Exhibit 37**. The Relator found a nearly identical breakdown of PBM market share when evaluating the plan options in the New York and Minneapolis areas.

432. Among available Part D plans in the Los Angeles area, the Relator found identical high beneficiary drug costs for all leading brand specialty drugs, including within the multiple sclerosis, anti-TNF and CML cancer

category. See **Exhibit 38**.

433. The uniform pricing of Part D drugs across the nation in these crowded, large-spending brand drug therapeutic categories is highly indicative of oligopolistic activity by drug manufacturers. In these maturing categories with modest prescription growth, 3-5 quite similar brand therapies (without direct generic alternatives) are available. Rather than competing aggressively for market share via discounts as would be expected in a normal functioning competitive market, the manufacturers are individually and collectively maximizing profits via severe price increases.

434. The staggering scale of the price inflation and resulting financial fraud has been abetted by similar oligopolistic activity by the PBMs that control the Part D program. In large spending, crowded brand therapeutic drug categories that require wide distribution, the Relator postulates that uniform collusive drug price levels are likely determined via contract negotiations between manufacturers and the leading market-share PBM Defendants, Express Scripts and CVS Caremark in most cases. In these large drug categories, the Relator presumes that the largest PBMs receive the most favorable *"percent of revenue"* service contract terms from manufacturers. Smaller PBMs with less leverage likely must accept the same drug price with less favorable service fee contract terms. However, with uniform drug pricing and severe systemic inflation, the majority of PBMs/specialty pharmacies with *"percent of revenue"* arrangements are likely receiving fraudulent compensation in Part D related to the BFSF scheme.

435. Of note, these industry dynamics likely do not apply for more unique specialty drug products, such as cancer therapies without direct competitors or orphan drugs. In these cases, manufacturers increasingly seek *"limited distribution"* arrangements with a small number of PBMs and/or specialty pharmacies. Historically, *"limited distribution"* drugs were mandated by the FDA for specific drugs with severe toxicity concerns that required close monitoring (i.e., FDA-mandated Risk Evaluation Management Systems, REMS programs).

436. Without any FDA restrictions, in the Relator's view, most recent *"limited distribution"* arrangements

between drug manufacturers and PBM/specialty pharmacies have been driven by financial rather than clinical issues. For unique drugs regardless of REMS needs, drug manufacturers have considerable negotiating leverage with PBMs and specialty pharmacies. In the service fee compensation model, manufacturers can enhance their profitability for unique drugs by paying lower *"percent of revenue"* rates to fewer PBMs/specialty pharmacies. The smaller number of relationships likely also simplifies the implementation of and benefit from price increases.

437. While the Relator's Qui Tam actions has focused on large brand therapeutic categories crowded with similar therapies, the potential for BFSF fraud with more unique drugs is also considerable. For example, in recent years, Express Scripts has been the exclusive distribution partner for both Jazz's Xyrem (for narcolepsy) and Questcor/Mallinckrodt's Acthar (for a variety of autoimmune conditions). The sales growth of both of these products has been primarily driven by massive price increases, rather than an increase in patient utilization. Express Scripts has likely received escalating service fee compensation related to these products, directly linked to the vast price inflation.

438. Of note, proof of collusive activity is not central to the false claim and kickback allegations in this Qui Tam case. Even if the Manufacturer and PBM Defendants successfully claim to be acting independently, the Part D regulations and legal precedent irrefutably require that BFSFs be paid at FMV.

MINIMAL DIFFERENTIATION AMONG PBM DEFENDANT *"SERVICES"*

439. All of the PBM Defendants routinely highlight the *"unique"* services, particularly regarding specialty drugs, that they provide to their payer clients, physicians and patients. However, industry expert feedback clearly indicates minimal differentiation in these services among the PBM Defendants. On January, 13, 2013, Goldman Sachs held a conference call with David Dross, the National Leader of the Managed Pharmacy Practice for Mercer, a leading health consultant firm that advises major corporations and health plans.

Regarding PBMs, the Goldman analyst concluded from the discussion: *"There is little differentiation among Specialty offerings". Goldman Sachs research note, 9/25/13.*

440. According to a January 2013 survey performed by Leerink Swann, a major healthcare investment firm, less than 5% of the health plans identified specialty drug capabilities as a key driver in its selection of a PBM. *Leerink Swann analyst report; PBM Survey Highlights of Key Trends, 1/22/13*. This same survey of 38 health plans indicated less than a 1% increase in client discounts between 2012 and 2013, indicating minimal price competition among PBMs.

441. The PBM Defendants cite high client retention statistics as an indication of their strong client support and satisfaction. As per PBM Defendant public disclosures, 90-97% of clients retain the same PBM when their multi-year contracts expire in any given year. In the Relator's view, high PBM Defendant client retention is a reflection of the minimal price competition regarding rapidly-inflating specialty drugs. With the cost of specialty drugs rising uniformly throughout the PBM industry, payers have little reason to endure the dislocation of switching PBMs.

442. However, the Leerink survey hinted at the large cost savings opportunity in a properly-functioning PBM marketplace. In the survey, among seven plans that were currently managing their drug costs on their own, four said they would consider hiring an outside PBM offering only a 5% cost savings benefit. Given the meteoric price increases for many older specialty drugs (with price increases averaging 10-25% per year), this modest level of savings would be easy to achieve for payer clients in a truly competitive marketplace.

443. As per website disclosures, the specialty drug service offerings of the PBM Defendants suggest minimal differences. See **Exhibit 39**. As per their specialty pharmacy websites, all three standalone PBMs, Express Scripts, CVS Caremark and Catamaran, provide nearly identical services across all specialty drug therapeutic areas, including the multiple sclerosis and anti-inflammatory categories. Key services provided to clients by all three PBMs for specialty drugs include express shipping, education/instruction, injection training, 24/7

on call phone support, assistance with prior authorization and convenient ordering. The PBMs list relatively few services that are provided to directly to drug manufacturers.

444. Drug manufacturers also directly provide extensive patient support services. A review of the drug websites of the Manufacturer Defendants (e.g., Humira.com, Lantus.com, Gleevec.com) indicates available support services that are identical to those offered by the PBM Defendants. As such, many potential services provided by the PBM Defendants for Medicare Part D beneficiaries may be redundant and therefore of no discernible value (i.e., a FMV of zero) to the Manufacturer Defendants. In addition, many services claimed to be performed by the PBM Defendants may actual be provided by the manufacturers.

PHYSICIAN INTERVIEWS INDICATE LIMITED CLINICAL ROLE OF PBM DEFENDANTS

445. The Relator's discussions with physicians indicate that the clinical claims of the PBM Defendants greatly overstates their limited role in day-to-day patient care. As part of this investigation, the Relator conducted interview with 20 leading physicians in the multiple sclerosis, rheumatoid arthritis and cancer therapeutic areas. In virtually all instances, the physicians indicated that the PBM Defendants primary role was to fill/deliver prescriptions and coordinate financial assistance. The need for patient financial assistance is now ubiquitous for specialty drugs after years of vast price inflation.

446. According to the physicians, for a patient newly-started on an injectable MS or anti-inflammatory specialty drug, the PBM Defendant/specialty pharmacy or the manufacturer may directly provide short duration injection training to patients. However, for patients chronically on specialty drugs, the physicians reported minimal clinical involvement of PBMs/specialty pharmacies. One physician described the clinical claims of PBM/specialty pharmacies as a *"gimmick to justify themselves."*

447. The physicians all stated that virtually all clinical management is done by themselves and their staff. In fact, numerous physicians stated that attempts at clinical intervention by centralized PBM/specialty pharmacy staff is often harmful, since the organizations have no personal contact with these typically complex patients. One physician stated that an attempt by a PBM a few years ago to directly contact patients for clinical reasons was quickly discontinued after his practice complained. The PBM was told that it *"had no right to interfere in the physician-patient relationship"*. Another physician tersely stated, *"If patients have a problem with their CML (chronic myeloid leukemia) drug, they call me, not an 800 number at a PBM or a specialty pharmacy"*.

448. Conversations with CML cancer experts uniformly indicated that PBM/specialty clinical services were even more scant for most oral specialty drugs. With uniform, vast inflation of all CMLs drugs, financial assistance, particularly for newly-started patients, was the key service coordinated through the PBMs/specialty pharmacies. Thereafter, the PBM/specialty pharmacy simply filled/refilled prescription via the mail, with minimal involvement in patient care. These physician discussions indicate a particularly high risk of *"sham"* services with *"percent of revenue"* service agreements for oral specialty drugs, particularly those linked to massive price inflation.

SPECIFICS OF FRAUDULENT DATA SUBMITTED TO CMS

449. Part D plan sponsors must provide detailed information to CMS in order to track performance, reconcile subsidy payments and to aid in the detection/prevention of fraud. In administering Part D, plan sponsors are required to submit PDE *("Prescription Drug Event"*) records for each prescription of all covered drugs dispensed to enrollees. The PDE includes more than 50 different fields of data, including end-user pharmacy drug cost data. Notably, the PDE includes the *"gross"* cost of a drug prescription, before rebates/discounts received from manufacturers.

450. The Relator alleges that the PBM Defendants have submitted a myriad of false claims to CMS with elevated drug costs driven by BFSF-related price levels. The Manufacturer Defendants have caused these false PDE submissions by paying fraudulent BFSFs to the PBM Defendants as part of this collusive pricing scheme.

451. The Relator alleges that all of the PDE data fields pertaining to drug costs and reimbursement include significant false claims data, since all items are predicated on fraudulently escalated *"negotiated prices"* due to the BFSF scheme. In **Exhibit 40**, the nine key PDE data fields most directly implicated in the current alleged fraud are listed; namely Fields 26 (Catastrophic Coverage Code), 27 (Ingredient Cost Paid), 30 (Gross Drug Cost Below Out-of-Pocket Threshold, 31 (Gross Drug Cost Above Out-of-Pocket Threshold, 32 (Patient Pay Amount), 33 (Other True Out-of-Pocket (TrOOP) Amount, Low-Income Cost-Sharing Subsidy Amount, 35 (Patient Liability Reduction to Other Payer Amount, and 36 (Covered D Plan Amount).

452. Other than PDE reports, the PBM Defendants, in their role as plan sponsors, have submitted false claims to CMS in the form of fraudulent "*Direct and Indirect Remuneration Reports*, DIR). Fraud has been committed by not reporting BFSFs in excess of FMV as DIR for the Manufacturer Defendant products. As stated previously, the risk of direct fraud detention has increased with escalating Part D BFSF and DIR reporting requirements since 2009.

453. For the vast majority of Part D plans, the PDE and DIR reports are prepared by PBMs, with limited controls or direct oversight by either CMS or unaffiliated plan sponsors. Furthermore, for most Part D plans, the sponsor, PBM and specialty pharmacy functions are provided by wholly-owned or closely affiliated PBM Defendants. As such, severe conflicts of interest and limited transparency undermine fraud prevention and detection in Part D.

454. The Part D regulations clearly indicate that plan sponsors, as well as PBM/specialty pharmacy subcontractors, are liable under the False Claims Act for fraudulent PDE data submissions to CMS due to

their requirement to *"certify"* compliance with regulations as a prerequisite for participation and payment. The provision of C.F.R. § 423.505, entitled *"Certification of data that determines payment"* states:

i. *General rule. As a condition of receiving a monthly payment under subpart G of this part (or fallback entities, payment under subpart Q of this part), the Part D plan sponsor agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of all data related to payment. The data may include specified enrollment information, claims data, bid submission data, and other data that CMS specifies.*

ii. *Certification of claims data. The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the claims data it submits….are accurate, complete, and truthful and acknowledge that the claims data will be used for the purpose of obtaining Federal reimbursement. If the claims data are generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, the entity, contractor, or subcontractor must similarly certify (based upon best knowledge, information and belief) the accuracy, completeness, and truthfulness of the data ad acknowledge that the claims data will be used for the purposes of Federal reimbursement."*

iii. *Certification of bid submission data. The CEO, CFO, or an individual delegated the authority to sign on behalf of these officers, and who directly reports to the officer, must certify (based on best knowledge, information, and belief) that the information in its bids submission and assumptions related to projected reinsurance and low income cost sharing subsidies is accurate, complete, and truthful and fully conforms to the requirements in § 423.265."*

iv. *Certification of allowable costs for risk corridor and reinsurance information. The Chief Executive*

Officer, Chief Financial Officer or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify (based on best knowledge, information, and belief) that the information provided for purposes of supporting allowable costs as defined in § 423.308 of this part, including data submitted to CMS regarding direct and indirect remuneration (DIR) that serves to reduce the costs incurred by the Part D sponsor for Part D drugs, is accurate, complete, and truthful and fully conforms to the requirements in § 423.336 and § 423.343 of this part and acknowledge that this is information will be used for the purposes of obtaining Federal reimbursement."

455. The legal liability of the PBM Defendants in this current filing was confirmed in recent case documents pertaining to another active Qui Tam case, the United States of America, ex. rel. Anthony R. Spay v. CVS Caremark Corporation (Civil Action No. 09-4672). In the Spay case, the Relator's company, Pharm/DUR, was hired by Medical Card System, Inc. (MCS, the second largest health administration and health insurance company in Puerto Rico) to perform a comprehensive audit of the Medicare Part D pharmacy claims paid by plan sponsor MCS for its Part D participants from January 1 through December 31, 2006. CVS Caremark provided PBM services to the health insurance plans offered by MCS. Spay alleged that CVS Caremark *"regularly and knowingly submitted false and fraudulent PDE data items to CMS"*. Spay alleged fraudulent PDE submission of inflated drug cost data and prescriber identification information, among other items, leading to false claims of more than $4 million.

456. In June 2011, the government notified the Court that it declined to intervene in the Spay matter. However, in September 2012, the government took the somewhat unusual step of filing a second Statement of Interest (pursuant to 28 U.S.C. § 517) *"to respond to certain arguments made by the defendants, Caremark, in their motion to dismiss the relator's complaint."* The Government provided its legal opinion prior to the Court case review regarding several key Part D topics germane to both the Spay case and this current Qui Tam filing.

457. First, the Government verified the *"certification"* requirements for both Part D plan sponsors and

participating subcontractors, including PBMs and specialty pharmacies. The Government stated:

> *"As a condition for receiving its monthly payment from CMS, a Part D plan sponsor must certify the accuracy, completeness and truthfulness of all data related to payment. Data related to payment may include enrollment information, claims data, bid submission data and any other data specified by CMS. 42 C.F.R. § 423.505(k)(l). If the claims data has been generated by a related entity, contractor, or subcontractor of a Part D plan sponsor, that entity, contractor or subcontractor must "similarly certify" that the claims data it has generated is accurate, complete and truthful and must acknowledge that the claims data will be used for the purposes of obtaining federal reimbursement. 42 C.F.R. § 423.505(k)(3). The term "claims data referred to in 42 C.F.R. § 452.505 (k)(3) includes PDE records."*
>
> The Government further stated:
>
> *"Part D plan sponsors must also certify in their contracts with CMS that they agree to comply with all federal laws and regulations designed to prevent fraud, waste, and abuse. 42 C.F.R. § 423.505(h)(l). CMS regulations require that all subcontracts between Part D plan sponsors and downstream entities, including pharmacies and PBMs contain language obligating the pharmacy to comply with all applicable federal laws, regulations, and CMS instructions." 42 C.F.R. § 42 3.505(i)(4)(iv).*

458. Second, the US Attorney in Spay definitively stated its position that PDEs are "*claims*" under the False Claims Act. The Government stated: *"On page 20 and 21 of their brief, defendants (i.e., Caremark) argue that "PDE data is not a claim under the FCA." Defendants are wrong."*

459. In its Statement of Interest for the Spay case, the Government also refuted Caremark's attempt to categorize PDE as a *"public disclosure"*. *"Accordingly, the United States does not believe that the*

circumstances in which PDE data may, under very restricted circumstances, be released to entities outside the government for research purposes, suggests that the submission of PDE information for purposes of Part D payment qualifies as a public disclosure under the False Claims Act."

460. On December 20th, 2012, the United States District Court for the Eastern District of Pennsylvania issued its Court Order denying Caremark's Motion to Dismiss the Spay Qui Tam Case. In the decision, the Court fully supported the Government's Statement of Interest determinations regarding plan sponsor and PBM liabilities under the FCA.

461. The Court determined that a primary basis for FCA violation in Part D is *"false certification"* of the *"truthfulness, accuracy and completeness"* of the data submitted by either plan sponsors or subcontractors (such as a PBM) as a *"condition of payment"*. Under the *"express false certification theory"*, an *"entity is liable under the FCA for falsely certifying that it is in compliance with regulations which are prerequisites to Government payment in connection with the claim for payment of federal funds."*

462. The Court included PBMs and other contractors as legally liable, stating: *"When the claims data is generated by a subcontractor of a Part D Sponsor, such as a PBM, the subcontractor must similarly certify, as a condition of payment, the truthfulness, accuracy and completeness of data". ."In turn, failure of either a Part D sponsor or the sponsor's subcontractor to submit accurate, complete and truthful data related to payment may give rise to a FCA claim"…"The Amended Complaint (in Spay) goes on to allege that, in violation of Section 423.505(k), Defendants then falsely certified the truth, accuracy, completeness of those data (i.e., PDE) fields. Such allegations give rise to a proper claim under the False Claims Act."*

463. CVS Caremark also argued in Spay that their PDE data submissions could not be false claims because the Defendant was paid by MCS, not directly by the government. Once again the Court disagreed. Because Part D *"certification"* required CVS Caremark's *"acknowledgement that the data will be used for the purposes of obtaining Federal reimbursement", "It is irrelevant that MCS, not Defendants, received the initial payment from CMS." …"Although CMS provides prospective payments to the Part D sponsor, who in turn prospectively pays the PBM, the PDE records are prerequisites to obtaining additional payments and to*

reconcile the accuracy of any previous payments made. Thus, because submission of a PDE is a condition of any future payment, a PDE is a claim or demand for payment under the FCA."

PART D BFSF FRAUD REFLECTED IN SKYROCKETING *"CATASTROPHIC"* SUBSIDIES

464. As stated previously, the BFSF pricing fraud is clearly reflected in the Part D spending trends since the start of the program. See **Exhibit 33.** First, the impact of traditional patent expirations and rising generic penetration is reflected in the moderate *"Regular Subsidy"* spending trends. The *"Regular Subsidy"* is an annual cost estimate provided by plan sponsors based upon a *"basic"* drug benefit for the average, relatively healthy Medicare Part D beneficiary. The majority of healthy elderly Part D beneficiaries use relatively few drugs and do not require expensive specialty drugs for severe medical conditions. Despite a 46% increase in Part D enrollment between 2006 and 2014, overall Part D *"Regular Subsidy"* payments only increased 6% from $17.6 billion in 2006 to $18.7 billion in 2014. As such, the *"Regular Subsidy"* amount per beneficiary declined 43% from $867 in 2006 to $496 in 2014. See **Exhibit 33**.

465. As noted previously, the government covers virtually all drug costs for "*Low Income Subsidy"* (LIS) Part D beneficiaries. This population includes elderly and younger disabled beneficiaries, 60-65% of whom are State "*dual-eligibles"* who qualify for both Medicare and Medicaid benefits. Prior to Medicare Part D, these *"dual-eligibles"* received their drug benefits via State Medicaid programs. Due to the poor health status of this population, Part D LIS beneficiaries in the early years of the program accounted for 70% of high-cost specialty drug spending, despite representing only 30% of the program's enrollment.

466. In addition to *"Regular Subsidy"* payments for these LIS beneficiaries, the government fully covers all additional costs for this population in the form of *"LIS Subsidy"* payments. While Part D sponsors provide estimates for *"LIS Subsidies"* in their annual plan bids, the plan sponsors bear no financial risk for any annual cost over-runs. CMS reimburses the plan sponsors for these additional costs following an annual

reconciliation process in the form of supplemental *"LIS Subsidy"* payments. As noted previously, the States are responsible for approximately 30% of LIS beneficiary drug costs through annual mandated "*clawback"* payments.

467. Between 2006 and 2014, Part D LIS enrollment increased by 42% from 8.3 million in 2006 to 11.8 million in 2014. Over this timeframe, annual program *"LIS Subsidy"* payments increased by 62% from $15.1 billion in 2006 to $24.3 in 2014. With these trends, the annual *"LIS Subsidy"* payment per LIS beneficiary increased by 13% from $1,817 in 2006 to $2,060 in 2014. See **Exhibit 33**. The increase annual *"LIS Subsidy"* payments reflects the cost benefit of numerous patent expirations, offset by severe price inflation for remaining brand traditional and specialty drugs.

468. The greatest driver of spending in Part D has been the large increase in annual *"Reinsurance Subsidy"* payments. In Part D, *"Reinsurance Subsidies"* are payments from CMS to cover 80% of drug costs for non-LIS beneficiaries that exceed the annual *"Catastrophic Threshold"*. The initial Part D annual *"Catastrophic Threshold"* was $3,600 in 2006, which gradually increased to $4,750 in 2013.

469. Key to this case, the annual spending threshold is very modest relative to the extreme cost of many specialty drugs, especially after years of severe price increases. For example, the monthly US cost of all available multiple sclerosis and rheumatoid arthritis therapies are now in the $6,000 and $4,000 range respectively, up from the $1,200 range in 2006.

470. As such, in Part D, at present any non-LIS beneficiary treated with even a single specialty drug will exceed the annual *"Catastrophic Threshold"* within the first several months of each year. Patients taking numerous traditional brand drugs, as is common with diabetics, can also quickly cross the annual *"Catastrophic Threshold"*.

471. Part D *"Reinsurance Subsidy"* payments have nearly quintupled from $6.0 billion in the first year of the program to $27.6 billion in 2014. The reinsurance subsidy cost per Part D beneficiary has increased by 147% from $297 in 2006 to $735 in 2014. As noted previously the staggering 44% single year increase in reinsurance subsidy payments in 2014 is consistent with the accelerating BFSF-related pricing fraud outlined in this complaint. See **Exhibit 33**.

VAST MANUFACTURER PART D PATIENT ASSISTANCE PROGRAMS (PAPs) CENTRAL TO FRAUD

472. In Medicare Part D, the majority of enrollees, other than LIS beneficiaries, face significant cost-sharing requirements, especially pertaining to high-cost specialty drugs. First, all non-LIS beneficiaries have an annual deductible before receiving any coverage. The annual deductible was $250 in 2006, rising to $325 in 2013. Second, after meeting the deductible, non-LIS Part D beneficiaries are responsible for 25% of drug costs before reaching the annual *"Initial Coverage Limit"*. The *"Initial Coverage Limit"* was $2,250 in 2006, rising to $2,970 in 2013. Taken together, the non-LIS beneficiaries are personally responsible for $750 and $986 of drug costs prior to the *"Initial Coverage Limit"* in 2006 and 2013, respectively.

473. Prior to 2011, non-LIS beneficiaries were then responsible for all drug spending between the annual *"Initial Coverage Limit"* and the annual *"Out-of-Pocket*" or *"Catastrophic Threshold"*. The difference between these two levels is commonly called the *"Donut Hole"*. Starting in 2011, manufacturers agreed to provide a 50% discount to beneficiaries in the *"Donut Hole"* window. The "*Catastrophic Threshold"* was $3,600 in 2006, rising to $4,750 in 2013. With these parameters, non-LIS Part D beneficiaries were responsible for $1,350 and $890 of *"Donut Hole"* drug costs in 2006 and 2013, respectively.

474. Combining deductibles, initial cost-sharing and *"Donut Hole"* exposure, a non-LIS Part D beneficiary was responsible $2,100 of drug costs prior to reaching the annual *"Catastrophic Limit"* in 2006, which fell modestly to $1,876 in 2013.

475. Given the extreme price inflation of many specialty drug since the start of Part D, an increasing number of non-LIS beneficiaries are quickly reaching these full out-of-pocket spending requirements. This process is further accelerated by significant cost-sharing requirements for specialty drugs in Part D. While most traditional brand drugs in a Part D formulary require a modest co-payment (typically in the $25-$75/prescription range), specialty drugs almost universally require a 25-30% non-LIS beneficiary co-insurance prior to the *"Catastrophic Threshold"*. As such, in Part D, virtually all non-LIS specialty drug-treated beneficiaries now have nearly $2,000 in cost-sharing requirements and surpass the annual *"Catastrophic Threshold"* in the first few months of each year.

476. In Part D, non-LIS beneficiaries are also still personally responsible for 5% of unlimited drug costs after exceeding the annual *"Catastrophic Threshold"*. With many Manufacturer Defendant specialty drugs now costing $40,000-70,000 per patient per year after severe price inflation, this exposure can be significant. For a $50,000 specialty drug, the non-LIS beneficiary would be responsible for an additional $2,500 in annual drug costs after exceeding the *"Catastrophic Limit"*.

477. Several extreme priced oral Part D specialty drugs carry far greater *"Catastrophic"* cost-sharing exposure for non-LIS beneficiaries. For instance, non-LIS Part D patients treated with Johnson &Johnson/Pharmacyclic's recently approved Imbruvica (for chronic lymphocytic leukemia), at a cost in the $132,000 range per patient/year, would be responsible for more than $6,000 in additional drug costs after exceeding the current *"Catastrophic Limit"*. In the hepatitis C space, with prices in the $70-90,000/patient range for Gilead's Sovaldi and AbbVie's Viekira, non-LIS Part D beneficiaries are responsible for approximately $3,300-3,800 in additional annual costs after exceeding the *"Catastrophic Threshold"*.

478. Including all cost-sharing requirements, an increasing number of non-LIS Part D beneficiaries have personal exposure in the $5,000 range or more per year. The patient cost-sharing exposure can be far greater for patients treated with multiple specialty drugs or newer extreme-priced drugs, such as for cancer or hepatitis. With the median income and savings for the average Medicare beneficiary in 2013 of $23,500 and

$61,400, respectively, these cost-sharing levels are beyond the financial capabilities of most non-LIS Part D beneficiaries. *Income and Assets of Medicare Beneficiaries, 2013-2030, Kaiser Family Foundation, January 9, 2014.*

479. However, despite the rising non-LIS beneficiary Part D cost-sharing burden associated with severe price increases and extreme-priced newer drugs, the outcry from patients has been relatively modest. This fact is reflected in high beneficiary satisfaction with the Part D program in surveys.

480. The Relator has determined that a vast expansion of manufacturer-funded Patient Assistance Programs (PAPs), especially for specialty drugs, has been a key factor deflecting attention from massive brand drug price inflation in Part D.

481. According to numerous Relator interviews with physicians in major specialty drug therapeutic areas (multiple sclerosis, inflammatory diseases and cancer), the vast majority of Part D patients treated with high-cost specialty drugs have virtually all of their cost-sharing responsibilities, including their 5% *"Catastrophic"* exposure, covered by manufacturers. The physicians reported hearing few complaints about drug costs from patients, with concerns mostly arising at the start of a calendar year when patients change insurance plans or benefits are altered. The physicians report that manufacturers work to quickly resolve such cases. Ironically, several physicians indicated that manufacturers have created a lot of *"good will"* with their *"seamless"* PAP operations.

482. While the Manufacturer Defendants tout the *"public good"* provided via their PAP programs, in reality, expanding patient financial support has been an essential, and highly profitable, part of the collusive pricing scheme. If Manufacturer's did not offset the cost-sharing requirements for most high-spending non-LIS beneficiaries, increased public scrutiny would likely have limited or prevented the massive three-six fold inflation for many of the Manufacturer Defendant drugs.

483. The Manufacturer Defendants also apparently receive considerable tax benefits for *"donated drugs"* in their PAP programs, whether administered directly by the company or through third-party charities. Ironically, the tax deduction is based upon the *"fair market value"* of the donated drugs. For the Manufacturer Defendant drugs, the FMV would generally be determined by the prevailing price in the marketplace. *"One way to obtain such information is to secure catalogs, brochures, or other documents that list prices of items which the donor sells in the ordinary course of business." In-Kind Contributions, Ronald Fowler and Amy Henchey, 1994.* As such, the Manufacturer Defendant tax deductions would increase along with the vast fraudulent price inflation as disclosed in the public AWP databases.

484. The manufacturer PAP programs also typically increase brand loyalty and limit patient treatment options. Due to annual renewal requirements and other PAP restrictions, patients are often hesitant to switch therapies, especially in high-cost specialty drug categories. Furthermore, with nearly uniform severe inflation and price levels in many of the brand therapeutic categories targeted in this case, physicians and patients have limited options to save money in the current environment.

485. CMS's limited oversight and favorable accounting treatment of PAP programs has also likely accelerated their use and drug price inflation. First, in Part D, CMS permits manufacturers to offset all beneficiary cost-sharing, including co-insurance for high-cost specialty drugs. Second, CMs has defined manufacturer PAPs as *"charities"*, therefore permitting their support to be applied to annual beneficiary TrOOP (True-Out-of-Pocket) spending limits prior to reaching the *"Catastrophic Threshold"*. Third, the Manufacturers can apply the full *"retail"* value of their assistance to beneficiary TrOOP limits, including free goods and cost-sharing forgiveness, thus significantly decreasing their true PAP program costs. Given the extreme prices of most specialty drugs, the manufacturer cost of production are typically less than 10% of the retail price.

486. The Patient Protection and Affordable Act of 2010 established a manufacturer Discount Program to help non-LIS Medicare Part D beneficiaries with their prescription drug costs during the coverage gap (i.e., *"Donut Hole"*). The Discount Program requires manufacturers to provide a 50% discount off the price for

brand-name drugs in the gap. CMS allowed manufacturers to apply the 50% discounts (again at full retail prices rather than actual cost) during the "*Donut Hole"* to the annual TrOOP limits. Once past the *"Catastrophic Threshold"*, the manufacturer receives full reimbursement of additional drug costs, with CMS covering 80% of the amount. With this TrOOP handling, manufacturers may have an incentive to further increase drug prices, thus undermining any potential cost savings from the new legislation.

487. CMS' own data indicates cause for concern. In September 2012, the GAO released a report *(GAO-12-914)* requested by Congress regarding the effect of the Discount Program on brand-name pricing trends. As part of the analysis, the GAO interviewed plan sponsors, PBMs and manufacturers; unfortunately the names of the organizations were not disclosed in the report. Six of the seven large plan sponsors (representing 68% of US Part D enrollees) and two of the three PBMs interviewed as part of the analysis said they thought the Discount Program *"may have been a contributing factor in the rising prices of brand-name drugs by some manufacturers"*. In contrast, six of the eight manufacturers *"believe that the prices of their brand-name drugs negotiated with plan sponsors and PBMs have not been affected by the Discount Program"*. Not surprising and consistent with the Relator's analysis, the PBMs indicated no role in the associated price inflation.

488. With Part D brand drug prices rising much faster that the modest increases in the *"Catastrophic Threshold"*, the profitability of manufacturer PAP assistance programs has accelerated each year in Part D. In 2006, with a typical specialty drug in the $10,000-15,000 annual cost range and the *"Catastrophic Threshold"* at $3,600, full offset of a non-LIS beneficiary's cost-sharing was quite favorable for a Manufacturer Defendant. However, in 2013, with the annual cost of the same drug now exceeding $50,000/year following severe price increases and a *"Catastrophic Threshold"* of $4,750, the Manufacturer Defendants' profit from full PAP cost-sharing support for the same patient is 4-5 times greater.

489. With ubiquitous cost-sharing support for high-cost non-LIS Part D beneficiaries, the Manufacturer Defendants, in turn, reap the full benefit of the massive price inflation from the *"Low-Income Subsidy (LIS)"*

Part D population. Historically, LIS Part D beneficiaries have accounted for 70% of Part D specialty drug spending which is virtually fully-funded by the government and taxpayers. However, in recent years, non-LIS beneficiaries have accounted for most of accelerating specialty drug spending, as reflected in skyrocketing *"Reinsurance Subsidies"*.

490. Of note, the vast expansion of manufacturer PAP spending in Part D has occurred despite considerable fraud concerns before the start of Medicare Part D. On November 22, 2005, the Office the Inspector General of the Department of Health and Human Services released in the Federal Register a publication entitled, *"Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D." Federal Register, Vol. 70, No. 224, 11/22/2005.* In the Advisory, HHS discussed in considerable detail its concerns regarding the potential anticompetitive impact of PAP programs in the Medicare Part D program. HHS stated: *"Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs, we believe such subsidies for Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse. Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (i.e., the subsidy) to beneficiaries to use its products."*

491. The OIG Advisory then goes on to discuss in considerable detail specific types of fraud that could result from PAP programs. As per the OIG document, *"The following are illustrative examples of some types of abuse that may occur:*

492. *"Increased costs to the program. We are concerned that a manufacturer might use beneficiary cost-sharing subsidies, which help beneficiaries meet their TrOOP requirements, to increase the number of beneficiaries using the manufacturer's product who reach the catastrophic benefit in any given coverage year and to hasten the point during the coverage year at which beneficiaries reach the catastrophic benefit. This is of particular interest because Medicare will make cost-based payments during the catastrophic coverage benefit. We know from experience that cost-based reimbursement is inherently prone to abuse,*

including by vendors that sell products reimbursed on a cost basis. Similarly, we are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices. Inflated prices could have a "spillover" effect on the size of direct subsides, reinsurance payments, and the risk corridor payments paid by Medicare in Part D plans in future years, potentially resulting in higher costs to the Medicare Program."

493. *"Beneficiary steering and anti-competitive effects. Subsidies provided by traditional pharmaceutical manufacturer PAPs have the practical effect of locking beneficiaries into the manufacturer's product, even if there are equally effective, less costly alternatives….Moreover, as we have previously noted in the Part B context, cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sale price for product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions."(Emphasis added)*

494. The Relator found independent investigation of manufacturer Part D PAP programs to be difficult for several reasons. First, CMS imposes no public reporting requirements regarding manufacturer PAP programs. As such, very few manufacturers disclose PAP information regarding either the private sector or government drug programs. Furthermore, the accuracy of any financial assistance data reported by manufacturers would be independently unverifiable. Second, the manufacturers can also fund PAP assistance via a wide array of third-party charities, which further decreases transparency.

495. An internet search for any brand drug typically leads to the manufacturer-controlled website. However, PBMs play a more central role in PAP programs for some manufacturers and drugs, but with typically little public disclosure. In all instances, the Manufacturer Defendant websites provide straightforward access to private sector drug coupons, but minimal website information regarding Part D PAP assistance. In order to obtain Part D information, beneficiaries are typically required to call a toll-free or to submit a referral document which includes financial information and physician authorization.

496. Of note, neither drug coupon nor PAP programs are means-tested. As such, while the manufacturers tout their aide to the poor and uninsured, the majority of the financial assistance is actually utilized to offset co-payment and/or co-insurance requirements for insured patients. Central to the scheme, the vast majority of the excessive drug costs related to fraudulent price inflation is borne by corporations/health plans (in the private sector) and by taxpayers in Part D.

497. Among the Manufacturer Defendants, Novartis is the only one that discloses any PAP financial information for specific products. Of note, the Relator determined that PBM Defendant Express Scripts is the direct contact for patient support for Novartis' CML cancer drugs, Gleevec and Tasigna, although this is not clearly disclosed. According its Annual Reports, Novartis' worldwide PAP spending for Gleevec has tripled from $417 million in 2006 to $1.215 billion in 2014. More recently, Novartis starting reporting PAP support specific for Tasigna; worldwide PAP for this drug doubled from $92 in 2012 to $185 million in 2014. Of note, these Novartis PAP amounts are based upon Wholesale Acquisition Cost (WAC) prices, which has vastly increased since the start of Part D. The actual dollar cost to Novartis for PAP programs is far lower, due to the low cost of manufacturing these straightforward, extreme-priced oral therapies. Much of the PAP assistance likely comes in the form of co-payment/co-insurance forgiveness and free goods.

498. On its patient assistance website, Manufacturer Defendant AbbVie states: *"In 2014, we assisted more than 110,000 patients by providing more than $851 million of prescription medicines."* AbbVie states that this estimate is based upon Wholesale Acquisition Cost (WAC). A large proportion of this assistance is likely related to Humira, which accounts for approximately two-thirds of AbbVie's sales.

499. The Relator expects investigation to uncover a similar vast expansion of PAP assistance programs related to other Manufacturer Defendant fast-inflating drugs. In SEC filings, PBM Defendants indicate that they receive compensation from manufacturers related to PAP programs. The Relator anticipates PAP programs to be an important area for investigation regarding fraudulent BFSFs, particularly pertaining to the 15% plan sponsor *"Catastrophic"* cost-sharing issue discussed in the next section.

500. The government's lack of restriction regarding manufacturer PAP programs in Part D is in stark contrast to its position regarding drug coupons. Drug coupons are widely used in the private insurance market by manufacturers, at the point of sale in the pharmacy, to offset beneficiary out-of-pocket costs. These coupons are now universally available to patients, including in print form distributed via physicians, electronically via a wide array of websites or by toll-free telephone numbers. In the private sector, drug coupons are now widely employed to offset the majority of patient out-of-pocket costs for many brand drugs, including for high-cost specialty drugs. According to an April 2015 IMS Institute report, 70% of private multiple sclerosis and rheumatoid arthritis patients now utilize *"drug coupons with terms that reduce out-of-pocket spend to nominal levels such as $5." Medicine Use and Spending Shifts, Report by the IMS Institute for Healthcare Informatics, April 2015.*

501. The Office of Inspector General of HHS forbids the use of drug coupons in Medicare Part D. The government's position was recently reiterated in a Special Advisory Bulletin in September 2014. The OIG stated: *"Pharmaceutical manufacturers offer copayment coupons to insured patients to reduce or eliminate the cost of out-of-pocket co-payments for specific brand drugs. These coupons constitute remuneration offered to consumers to induce the purchase of specific items. When the item in question is one for which payment may be made, in whole or in part, under a Federal health care program (including Part D), the anti-kickback statute is implicated."*

502. The fraud concerns regarding drug coupons and PAP programs in Part D would appear to be super imposable. The OIG extensively documented its fraud concerns regarding PAPs in its 2005 Advisory prior to the start of the program. In the Relator's view, virtually all the government's concerns have come to fruition on a grand scale in the first decade of the Part D program. Despite the evidence, no significant federal regulations, limitations, reporting requirements or oversight have ever been placed on manufacturer PAP programs in Medicare Part D. Furthermore, HHS has not publicly-released any analysis or further broad commentary on Part D PAPs since the program began.

503. In the Relator's view, the vast expansion of both private drug coupons and Part D PAPs is closely linked to BFSF-related pricing fraud in the Part D program. *"The use of such co-payment cards and coupons and other types of discounts has more than tripled since mid-2006, according to IMS Health." Andrew Pollack, New York Times, January 1, 2011.* Increased financial assistance across both private and government insurance plans has been essential to insulate patients from unaffordable cost-sharing exposure and to lessen public scrutiny. In most instances, payers, rather than beneficiaries, have funded the vast majority of escalating drug costs driven by the fraudulent pricing scheme between drug manufacturers and PBMs.

504. The PBM Defendants claim that they have no ability to alter the use of manufacturer drug coupons in the private sector. The Relator believes this to be a deceitful claim. In fact, cooperation between the Manufacturer Defendants and PBM Defendants regarding PAP programs in Part D and coupon programs in the private sector is essential to success of the BFSF pricing scheme.

505. The public rhetoric regarding drug coupons provides a prime example of the *"false"* adversarial relationship that the Defendant parties have fostered to deflect attention from their collusive pricing scheme. Both Defendant parties have been ably assisted by their respective trade organizations, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Pharmaceutical Care Management Association (PCMA). Among the Manufacturer Defendants, the CEOs of AbbVie, Sanofi, Bristol-Myers Squibb, Amgen, Johnson & Johnson, Pfizer and Novartis currently serve on the PhRMA Board of Directors. Among the PBM Defendants, the CEOs of Express Scripts and Catamaran (now part of UnitedHealth Group) currently serve on the PCMA Board of Directors. The PCMA Board of Directors also includes senior executives from PBM Defendants CVS Caremark, Aetna, Humana and Cigna.

506. In November 2011, the PCMA paid a consulting firm, Visante, to generate a report regarding drug coupons. *How Copay Coupons Could Raise Prescription Drug Costs by $32 Billion Over the Next Decade. November 2011.* In the article, the PCMA placed the full blame for coupon abuse on drug manufacturers. The PCMA stated that manufacturer coupon programs undermine formulary and copay incentives, which

"are important tools used by health plans and pharmacy benefit managers (PBMs) to encourage price competition and reduce drug costs." However, the PCMA report concluded that PBMs could not prevent the use of coupons due to the *"shadow claims system"*.

507. As per the PCMA report, *"regardless of the distribution model, copay coupons are all invisible to the payer and PBM, because they all occur after the adjudication of the prescription. That is, the pharmacy sends the claim through the switch, to the PBM. The PBM adjudicates the claim and sends the necessary information back through the switch to the pharmacy, including the dollar amount to be paid by the payer plus the copay amount to collect from the patient. Then, after the PBM has sent this information, the coupon program reduces the copay due from the consumer. Thus, copay coupon programs act as a "shadow claims system" that facilitates consumers using more expensive drugs instead of less expensive drugs. Payers have no easy way to detect transactions taking place through this "shadow claims system".*

508. The PCMA report made no mention of the long-standing, wide use of internal PBM mail order pharmacies for dispensing chronic care traditional drugs. As such, for key traditional drug categories, such as diabetes, the PBM Defendants have direct access to a significant portion of pharmacy transactions regarding drug coupons.

509. In the 2011 report, the PCMA excluded specialty drugs from their estimates of manufacturer coupon abuse *"because copay offset programs on specialty products do not undermine generics and manufacturer price concessions to health plans in the same way that copay coupons on non-specialty brands do"*.

510. However, the Relator has determined that coupon abuse with extreme-priced specialty drugs has been severe and accelerating along with the vast price increases. Furthermore, the PBM Defendant claims that lack of pharmacy transparency prevents their intervention is mute regarding specialty drugs. In both the private sector and Medicare Part D, the vast majority of specialty drugs are dispensed by centralized specialty pharmacies, most of which are either wholly-owned or closely affiliated with the PBM Defendants. As such

for the majority of specialty drugs, the PBM Defendants have complete access to all coupon utilization data, while not sharing the data with either private clients or CMS. According to IMS, 75% and 65% of anti-inflammatory and CML cancer specialty drugs, respectively, were dispensed via specialty pharmacies in 2014, up from 55% and 50%, respectively, in 2010.

511. The PBM Defendants market share and control of the specialty pharmacy segment has escalated in recent years with the promotion of narrow pharmacy networks. In the private sector, the PBM Defendants increasingly require that beneficiaries fill all specialty prescriptions via their centralized specialty pharmacies. While Medicare Part D's *"Any Willing Provider"* provision prevents outright pharmacy exclusive, the PBM Defendants can place significant financial incentives to drive beneficiaries to use their internal specialty pharmacies. The PBM Defendants tout that *"narrow networks"* save client money, which may be marginally true since smaller specialty pharmacies lack the negotiating leverage for even modest rebates/discounts with manufacturers. However, fraudulent manufacturer service fees tied to severe specialty drug price inflation are the primary driver of the PBM Defendants efforts to consolidate specialty drug distribution.

512. According to a leading industry expert, *"approximately 75% of Medicare beneficiaries in 2014 enrolled in a Part D plan with a preferred network design, up from 43% of beneficiaries that chose plans with narrow networks in 2013." Adam Fein, Managed Care Access, The Future of Drug Coupons and Co-Pay Cares, October 8, 2014.* With these market dynamics, the dominant PBM Defendants could easily restrict the use of manufacturer drug coupons in the private sector, particularly for specialty drugs, if they were acting in good faith for their payer clients.

513. In September 2014, the OIG issued a report entitled *"Manufacturer Safeguards May Not Prevent CoPayment Coupon Use for Part D Drugs." OEI-05-12-00540, September 2014.* While manufacturers have been successful in blocking drug coupon use in Part D, the report noted some tracking limitations that have prevented complete exclusion. However, the OIG appeared not to recognize the current market dynamics

pertaining to PBMs, specialty pharmacies and specialty drugs. In fact, none of these three terms is even mentioned in the report.

514. The OIG supported the PBM Defendant contention that they cannot influence the use of drug coupons. As per the report, *"It is difficult for entities other than manufacturers to identify coupons as they are processed through the pharmacy claims transaction system or after they are adjudicated. Coupons are not transparent in the pharmacy claims transaction system to entities other than manufacturers."* As with other federal evaluations in recent years, the OIG failed to recognize that, in Part D, the plan sponsor, PBM and specialty pharmacy functions are provided by the same or closely-affiliated entities for the vast majority of beneficiaries.

515. Soon after the PCMA report, in January 2012, the PhRMA issued its own paid consultant-generated (Amundsen) report touting the benefits of drug coupons. One of the key conclusions of their independently-unverifiable analysis was that *"most money invested by US branded pharmaceutical companies into copay card offset programs goes into specialty and biologic products or therapies that have no available generic alternatives and benefit the PCMA's members as much as the pharmaceutical companies.." Pharmaceutical Executive, Mason Tenaglia, Amundsen Group, January 2012.*

516. A few other notable quotes from the PhRMA report:

- *"Collectively, we estimate that specialty products represent just over 51% of the total annual spending on co-pay card programs and coupons."* No doubt the role of specialty drugs in coupon programs has further escalated in the nearly four years since this report was written.

- *"Specialty Tier cost-sharing can be particularly onerous due to the incidence of co-insurance and deductibles for both contracted and non-contracted brands."*

- *"In the largest specialty classes (TNF inhibitors, MS, Oncology) we observe that between 5 and 15*

percent of new commercially insured patients may be exposed to co-insurance or copayments greater than $400 per month regardless of the branded product's contract status...In the absence of copay card offset programs, as many as one-third of these patients would be abandoning their initial prescriptions."

- *"In Medicare Part D, Amundsen has analyzed more than a dozen specialty products where the Standard Eligible population will face a "specialty tier" copay of more than $300 per prescription. Over a third of those patients will "abandon" their prescription."*

- *"Copay card programs are one of the best places for a pharmaceutical company to invest. And the fact that the returns are as high as 4:1 (and up to 6:1) is an indication of how valuable the offers are to patients.*

- *As with specialty coverage, employers and insurers should be thanking pharmaceutical marketers for the help in getting - and keeping - patients on their medications."*

517. Neither the PCMA nor the PhRMA reports make any mention of the role of severe price increases pertaining to expanding drug coupon and PAP programs in recent years. Both Defendant parties seek to create confusion and project blame for financial assistance programs that have been essential for their mutually-beneficial fraudulent pricing scheme. In the Relator's view, the Defendant parties' rhetoric around drug coupons further illustrates the centralized, long-standing and intentional nature of the vast fraud outlined in this complaint.

LIKELY FRAUD RELATED TO PLAN SPONSOR UNLIMITED CATASTROPHIC COST-SHARING

518. Part D also incorporated cost-sharing mechanisms for plan sponsors in Part D. While CMS covers 80% of drug costs in the *"Catastrophic"* phase, plan sponsor are responsible for 15%, with the remaining 5% theoretically paid by beneficiaries. In a properly functioning market, this considerable unlimited cost

exposure should have highly-incented plan sponsors to employ long-established cost-savings tactics, including formulary restrictions and *"therapeutic substitution"* programs, with specialty drug manufacturers. However, with vertical integration of plan sponsor/PBM/specialty pharmacy functions in Part D, the PBM Defendants have instead achieved far greater profits by participating in a price inflation scheme with the Manufacturer Defendants.

519. Similar to the situation with beneficiaries, the accelerating cost-sharing financial responsibilities for the PBM Defendants (in their roles as Part D plan sponsors), driven by severe price inflation, appear onerous. For instance, in 2013, the plan sponsor 15% cost-sharing burden for a Part D beneficiary on a single $50,000 specialty drug would be $6,800 in the *"Catastrophic"* phase after exceeding the $4,750 annual spending threshold.

520. At the aggregate Part D level, plan sponsor *"Catastrophic"* cost-sharing exposure has nearly quintupled between 2006 and 2014 along with the rise in "*Reinsurance Subsidy"* payments. The CMS-reported *"Reinsurance Subsidies"* correspond to $7.5 billion in total Catastrophic Part D spending (120% of the *"Reinsurance Subsidies"*) in 2006, rising to $34.8 billion in 2014. At a 15% rate, the Part D plan sponsor cost-sharing burden associated for *"Catastrophic"* spending has risen from $1.1 billion in 2006 to $5.2 billion in 2014. Cumulatively, non-LIS Part D *"Catastrophic"* plan sponsor cost-sharing requirements were nearly $22 billion in the first nine years of the Part D program. See **Exhibit 41**.

521. To put the magnitude of this plan sponsor cost-sharing burden in perspective, the Part D plan bids for all sponsors across the nation in 2007 included *"expected profits"* of only $1.07 billion. *GAO Report OEI-02-08-00460, Medicare Part D Reconciliation Payments for 2006 and 2007, September 2009.* In the Relator's view, there is no mathematical possibility that the PBM Defendants could handle these massive *"Catastrophic"* cost-sharing requirements associated with severe price increases, without the majority being offset by drug manufacturers. Of note, this GAO report is the only federal document the Relator has been able to locate that mentions Part D plan sponsor profits.

522. The Relator has identified two potential mechanisms for manufacturers to offset these fast escalating PBM Defendant cost-sharing requirements, both of which appear fraudulent. Most likely, manufacturers of some high-cost specialty drugs are paying far higher *"percent of revenue"* service fee rates, inclusive of price increases, to the PBM Defendants. In the Relator's view, this pathway would simply escalate the magnitude of FMV BFSF fraud. BFSFs in excess of FMV should have been reported to CMS as drug discounts in annual DIR reports.

523. Second, the manufacturers may be providing other forms of hidden payment to the PBM Defendants to cover much of their 15% exposure, including free goods or grants. However, the regulations indicate that such payments would be also be discounts that must be reported in annual DIR reports.

524. Unfortunately, Part D does not require direct reporting of the plan sponsor *"Catastrophic"* 15% cost-sharing requirements either in PDE or DIR reports. In the *"Catastrophic"* phase, the PBM Defendant/plan sponsor reports 95% of drug costs (all other than the beneficiary 5% cost-sharing) in the PDE report. This amount is apparently reported in field 38 of the PDE report, entitled *"Covered D Plan Paid Amount, (CPP)"*. After the plan year, CMS then reconciles actual plan spending, including the *"Catastrophic"* portion, with the sponsor bid made prior to the start of the year. CMS will reimburse the plan sponsor for 80% of its annual *"Catastrophic"* spending. CMS does not appear to have a direct mechanism to monitor any payments or economic transfers between manufacturers and the PBM Defendants/plan sponsors related to the plan sponsor 15% *"Catastrophic"* cost-sharing requirement.

525. With these limitations, the accounting of the PBM Defendant 15% non-LIS cost-sharing requirements remains a major outstanding issue of the Relator's investigation. Due diligence will require careful scrutiny of all economic transfers between the Manufacturer Defendants and the PBM Defendants, including their related subsidiaries and partnerships.

526. In the Relator's view, the acceleration in Part D *"Catastrophic"* spending over the two most recent

program years suggests accelerating fraud related to PBM Defendant *"Catastrophic"* cost-sharing requirements. Driven by severe price increases and surging hepatitis C costs, Part D non-LIS *"Catastrophic"* annual spending has increased by 75% in just two years, from $19.6 billion in 2012 to $34.8 billion in 2014. The plan sponsor 15% cost-sharing portion has similarly risen from $2.9 billion in 2012 to $5.2 billion in 2014.

527. Despite the unexpected surge in hepatitis C spending, none of the major PBM Defendants reported a significant negative financial impact from rising Part D *"Catastrophic"* spending in 2014. The notable exception was the smaller PBM Defendant, Wellcare, which reported cost over-runs in 2014, which will lead to additional reinsurance subsidy payments from CMS during reconciliation for the plan year. Of note, Wellcare's financial troubles were likely a key factor leading to its November 2014 mail order partnership with CVS Caremark.

PBM DEFENDANT SEC RECONCILATION DISCLOSURES SUGGEST COLLUSION/FRAUD

528. The Relator views recent corporate disclosures from PBM Defendants CVS Caremark and Wellcare as indicate of systemic collusion with drug manufacturers in Part D. In its 2013 annual report, PBM Defendant CVS Caremark states*: "Significant estimates arising from our participation in the Medicare Part D program include: (i) estimates of low-income cost subsidy and reinsurance amounts ultimately payable to or receivable from CMS based on a detailed claims reconciliation, (ii) an estimate of amounts payable to CMS under a risk-sharing feature of the Medicare Part D program design, referred to as the risk corridor and (iii) estimates for claims that have been reported and are in the process of being paid or contested and for our estimate of claims that have been incurred but have not yet been reported. Actual amounts of Medicare Part D-related assets and liabilities could differ significantly from amounts recorded. Historically, the effect of these adjustments has not been material to our results of operations or financial position."*(Emphasis added)

529. Similarly, in its 2013 10-K on file with the SEC, PBM Defendant Wellcare states: "*Historically, we have not experienced material adjustments related to CMS annual reconciliation of prior year low-income cost sharing, catastrophic reinsurance subsidies and coverage gap subsidies."* (Emphasis added)

530. Due to the long time horizon between annual Part D sponsor bids and reconciliation, these disclosures suggests widespread collusion and fraud between these PBM Defendants and drug manufacturers in Part D. Medicare Part D requires plan sponsors to submit plan bids six months prior to the effective date of the subsequent calendar plan year, with reconciliation 27 months later. As stated in the PBM Defendant Humana's 2013 10-K: *"Settlement of the reinsurance and low-income cost subsidies as well as the risk corridor payment (for the "Regular Subsidy") is based on a reconciliation made approximately 9 months after the close of the year. This reconciliation process requires us to submit claims data necessary for CMS to administer the program."*

531. In Part D, CMS and plan sponsors share either excess profits or costs for annual spending that is +/- 5% greater than bid forecasts in a given plan year. As such, these SEC disclosures indicate that both a dominant PBM in Part D (CVS Caremark) and a far smaller one (Wellcare) have been able to accurately forecast *"Catastrophic"* spending in their Part D plans since the start of the program, despite massive price increases and accelerating cost trends. Wellcare apparently did not run into forecasting problems until the 2014 plan year. The Relator has not found specific disclosures from the other PBM Defendants regarding the reconciliation process, but none has reported significant financial shortfalls related to Medicare Part D.

532. The astounding plan bid accuracy of the PBM Defendants suggests they either have extensive knowledge of both the magnitude/timing drug price increases or the majority of unanticipated Part D cost overruns are being covered by drug manufacturers.

THERAPEUTIC CATEGORY/PRODUCT BACKGROUND

Anti-Tumor Necrosis Factor (TNF) Category:

533. Self-injected anti-TNF specialty drugs are leading biologic therapies for several major inflammatory conditions, including rheumatoid arthritis, Crohn's disease, ulcerative colitis and psoriatic arthritis. In the US the ant-TNF market has long been dominated by two products, Amgen's Enbrel (enterecept, FDA approval 1997) and AbbVie's Humira (adalimumab, FDA approval 2003). Both Enbrel and Humira act by blocking tumor necrosis factor (TNF), a cytokine that plays a key role in inflammatory processes and resulting joint damage. While the clinical profiles of the drugs are quite similar, Humira has steadily been taking market share from Enbrel over the past decade, primarily due to a modestly improved dosing schedule (a biweekly injection versus weekly for Enbrel) and a greater number of medical indications. Humira is approved for Crohn's disease and ulcerative colitis in the US, while Enbrel is not.

534. In recent years, two additional anti-TNF therapies, UCB Group's Cimzia (certolizumab, FDA approval 2008) and Johnson & Johnson's Simponi (golimumab, FDA approval 2009) have become available. Both of these new products offer clinical profiles similar to Enbrel and Humira, with dosing advantages over both of the older anti-TNF agents. The maintenance doses for both Cimzia and Simponi are given monthly. In addition to the large rheumatoid arthritis indication, Cimzia is approved for the treatment of Crohn's disease and Simponi is approved for the treatment of ulcerative colitis. An intravenous anti-TNF therapy, Remicade (infliximab, Johnson & Johnson, FDA approval 1998) is also marketed in the US for the treatment of rheumatoid arthritis, Crohn's disease, ulcerative colitis, psoriasis and psoriatic arthritis. Remicade is not implicated in this case because it is reimbursed via Medicare Part B, not Part D. In 2009, Johnson & Johnson also received approval for an infusional version of Simponi, called Simponi Aria. This formulation is similarly reimbursed via Medicare Part B and not implicated in this case.

535. The FDA-approved prescribing information for these subcutaneous four anti-TNF therapies indicate very similar clinical profiles. See **Exhibit 42**. In comparing the agents, all four provide very similar clinical benefits in rheumatoid arthritis, as measured by standard American College of Rheumatology (ACR) criteria. The side effect profiles of the drugs are virtually identical and all carry a *"Black Box"* safety warning from the FDA regarding the risk of rare severe infections and malignancies.

536. Furthermore, medical experts consider the clinical profiles of these four subcutaneous anti-TNF therapies to be clinically-interchangeable. In fact, leading US medical organizations do not discern between the products in their clinical guidelines. In its 2012 updated guidelines for the treatment of rheumatoid arthritis, the American College of Rheumatology states*: "If a patient has moderate or high disease activity after three months of methotrexate monotherapy or DMARD combination therapy….the panel recommends adding or switching to an anti-TNF biologic, abatacept or rituximab." 2012 Update of the 2008 American College of Rheumatology Recommendations for Disease-Modifying Antirheumatic Drugs and Biologic Agents I the Treatment of Rheumatoid Arthritis, Arthritis Care & Research, Vol. 64, No. 5, May 2012, pp. 625-639.*

537. The major US medical organization clinical guidelines for Crohn's disease also does not separate the three anti-TNF therapies that are approved for use. According to the American Gastroenterological Association Crohn's disease guidelines: *"We recommend using ant-TNF-alpha drugs to induce remission in patients with moderately severe Crohn's disease who have not responded to standard therapies. As a group, the three anti-TNF-alpha drugs that are FDA-approved for the treatment of Crohn's disease (infliximab, adalimumab and certilizumab) are more likely than placebo to induce remission in patients with moderately severe Crohn's disease refractory to standard therapies." The AGA Institute Clinical Practice and Quality Management Committee, published March 04, 2014.*

538. Regarding ulcerative colitis, the American College of Gastroenterology practice guidelines recommend the preferential use of intravenous Remicade for severe cases, without any preferences among the

subcutaneous anti-TNF options. *American College of Gastroenterology, Clinical Guidelines for Ulcerative Colitis in Adults, Am J of Gastroenterol, 2010; 105.*

539. The availability of four clinically-similar subcutaneous ant-TNF drugs provides considerable leverage for the dominant PBM Defendants in their negotiations with manufacturers. However, pricing, volume and sales trends in the category suggest significant anti-competitive activity in Part D and the private insurance marketplace. As previously indicated in **Exhibit 6**, the AWP list price for all four anti-TNF therapies has increased severely and in virtual lock-step over the past 5-6 years. Just since 2010, the average annual cost per patient (at labeled maintenance doses) has increased from the $24-26,000 range to the $45-50,000 range. Before 2010, the annual cost of Enbrel and Humira increased sharply from the $17,000/year range just before the start of Part D. With PBM Defendant service fee contracts structured as a *"percent of revenues"*, Part D BFSF payments from manufacturers have greatly escalated along with the price increases.

540. The Relator alleges that fraudulent BFSF arrangements between the Manufacturer and PBM Defendants is the primary driver of this anti-competitive pricing activity in the US anti-TNF category. The Relator alleges that the vast majority of the severe US price inflation for the four- anti-TNF products would not have occurred in a properly-functioning competitive marketplace, in which the PBM Defendants use straightforward formulary strategies to gain favorable prices for their clients in exchange for market share.

541. In the dysfunctional Part D program driven by fraudulent BFSF compensation and price increases, the PBM Defendants are rather incented to preserve the market share of the market leaders, while all products in the category benefit from severe price increases. The PBM Defendants have little interest in disrupting the revenue stream from market leaders, which would result in lower BFSFs and larger discounts reported to CMS.

542. As mentioned in the discussion of Express Scripts' *Drug Trend* reports, recent trends suggest accelerating pricing fraud in numerous US drug categories, including the US anti-TNF market. Within Defendant Express

Scripts' Medicare clientele, in 2013 and 2014, price increases accounted for 70-80% of the Humira's 17-24% annual spending growth. Within Express Scripts, price increases for Amgen's Enbrel accounted for 96% of the product's spending growth between 2010 and 2014.Within Express Script's Part D clientele since the start of 2013, the cost per patient for Enbrel rose 30% while utilization declined -3.7%.

543. The high reliance of both Defendant parties on the anti-TNF category and its individual products for growth has likely contributed to magnitude of the pricing fraud. As per the Express Scripts *Drug Trends Reports*, the anti-inflammatory category is the third highest specialty drug category in the US, after cancer and multiple sclerosis. At Express Scripts, Enbrel and Humira were the fourth and fifth top-spending specialty drugs in Medicare Part D in 2014. For Defendant AbbVie, Humira accounted for 65% of the company's US revenues in 2014 and far greater share of its profits and growth.

544. The Relator alleges that the vast majority of price inflation in the US anti-TNF category since the start of Part D would not have occurred without fraudulent BFSF incentives. The Relator's direct BFSF fraud payment estimate is based upon manufacturer-reported US sales, using a standard contract rate estimate. The direct BFSF fraud would be greater based upon higher AWP pricing levels.

Chronic Myeloid Leukemia (CML) Category:

545. Chronic Myeloid Leukemia (CML) is a form of leukemia characterized by the increased and unregulated growth of predominantly myeloid (white blood) cells. CML is caused by the translocation of a specific gene (ABL) from one chromosome (9) to another (22). In the United States, the average age of diagnosis is 60-65 years old, with approximately 4,600 new cases per year.

546. Over the past 15 years, the long-term survival of CML patients has markedly improved with the arrival of breakthrough targeted oral therapies, called Tyrosine Kinase Inhibitors (TKIs). The first TKI drug,

Novartis' Gleevec (imatinib), quickly gained wide use following its US approval in 2001. Two additional TKIs have been approved for the treatment of CML over the past decade, namely Bristol-Myer's Squibb's Sprycel (dasatinib, US approval 2006) and Novartis' follow-up therapy, Tasigna (nilotinib, US approval 2007). In more recent years, two additional TKI CML therapies have been approved in the US, Pfizer's Bolsulif (bosutinib) and Ariad's Iclusig (ponatinib). The use of these latter two agents is primarily restricted to the smaller refractory CML population due to toxicity issues.

547. Both Sprycel and Tasigna were initially approved for the treatment of CML patients refractory to Gleevec therapy, but both gained expanded labelling for newly-diagnosed CML patients in 2010. According to their FDA-approved labels, both Sprycel and Tasigna have demonstrated superior clinical responses in short-term head-to-head trials vs. Gleevec. See **Exhibit 43**.

548. According to the leading US CML medical organization, the Leukemia and Lymphoma Society (LLS), *"Findings from studies of each drug* (Sprycel and Tasigna) *show faster complete cytogenic response (CCyR) and molecular response (MR) than the response with Gleevec. These drugs may prove to be associated with better long-term outcomes." Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org*. However, the LLS document further states: *"neither Sprycel nor Tasigna has been shown to result in longer survival"* (than Gleevec).

549. Pending long-term comparative survival data, all three TKIs remain viable first-line CML therapies. The LLS also indicates that the tolerability of both Sprycel and Tasigna compares favorably to Gleevec. *"In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Sprycel"*. Similarly, *"In a one-to-one comparison with Gleevec, most side effects were reported less commonly in patients treated with Tasigna". Leukemia and Lymphoma Society Chronic Myeloid Leukemia Information Booklet, Revised 2014, www.LLS.org*.

550. With these favorable clinical profiles, both Sprycel and Tasigna have steadily gained market share from Gleevec over the past decade. Gleevec's US total prescription share among these three leading CML drugs declined from 100% at the start of Part D to 85% at year-end 2010 and 65% at year-end 2014. See **Exhibit 11**. The market shares for Sprycel and Tasigna reached 9% and 6%, respectively, in 2010 and 17% and 16%, respectively, in 2014. According to IMS, Gleevec's US prescriptions have increased only an average of 1% per year since 2010, as Sprycel and Tasigna have gained market share. The overall US CML prescription market has grown an average of 7% per year between 2010 and 2014.

551. Despite eroding usage trends, Novartis has reported consistent robust US Gleevec sales growth in recent years driven by severe price increases. Novartis' reported annual US Gleevec sales have increased from $525 million in 2005 to $1.3 billion in 2010 and $2.2 billion in 2014. Since 2010, virtually all of Gleevec's revenue growth has been driven by severe price increases. Based upon IMS prescriptions, Novartis received nearly $103,000 per Gleevec-treated US patient in 2014, up from approximately $60,000 in 2010. See **Exhibit 12**. The Relator alleges that the vast majority of Gleevec's US price inflation has been driven by fraudulent BFSF incentives in Part D.

552. Both Sprycel and Tasigna have also exhibited significant price inflation along with Gleevec in recent years. Based upon Novartis' corporate-reported US sales and IMS prescriptions, Tasigna yielded $96,000 per patient in 2010, rising to $105,000 in 2014. Based upon Bristol-Myers Squibb's corporate-reported US sales and IMS prescriptions, Sprycel yielded $86,000 per patient in 2010, rising to $120,000 in 2014.

553. The Relator's investigation also indicates a greater likelihood of BFSF fraud with most oral specialty drugs compared to injectable therapies. With oral drugs, many of historic specialty services, such injection training, and special handling/shipping are not necessary. As such, *"percent of revenue"* service contracts tied to price increases are particularly inappropriate with extreme-priced oral specialty drugs. The Relator's discussions with physician experts indicated that the PBM Defendants provided few services to CML patient

other than routine shipping/refill reminders and financial assistance referrals. Ironically, financial assistance has increasingly become essential due to the severe price inflation at the center of this case.

554. Several key factors escalate the estimated magnitude of Part D fraud in the US CML market. First, as with most cancers, CML is a disease primarily of the elderly. Based upon physician expert discussions, the Relator estimates that 55% of the prescriptions for Gleevec, Sprycel and Tasigna are written for Part D beneficiaries. Second, as an oral therapies, the CML category, dominated by Gleevec, has long been a key cost driver in Part D. In contrast, injectable cancer drugs are reimbursed via Medicare Part B. As per the 2014 Express Scripts *Drug Trend Report,* Gleevec is the second highest spending Part D cancer drug, after Celgene's multiple myeloma therapy, Revlimid. See **Exhibit 32**. Third, the Relator alleges significant BFSF related to oral CML drugs due to their extreme prices, severe price increases and limited legitimate services being provided by the PBM Defendants, as per discussions with CML physician experts.

Diabetes Category:

555. As mentioned previously, the US diabetes therapeutic category includes four major brand categories, including two oral segments and two injectable segments. The two major oral segments are DPP-4 inhibitors and SGLT-2 inhibitors. The two major injectable segments are GLP-1 agonists and insulins. Following an array of recent new product approvals, all four of these segments now have 4-5 clinically-interchangeable drugs that should afford considerable negotiating leverage and cost-savings potential.

556. In the DPP-4 category, since 2011, three new drugs with various formulations, Astra Zeneca's Onglyza/Kombiglyze XR (saxagliptin, FDA approval 2009), Boehringer Ingelheim's Tradjenta/Jentadueto (linagliptin, FDA approval 2011) and Takeda's Nesina/Oseni/Kazano (alogliptin, FDA approval 2013) have been launched. These new entrants now compete directly with the long-standing market leader, Merck's Januvia/Janumet (sitagliptin, FDA approval 2006).

557. According to the products' FDA-approved labels, the clinical profiles of these four DPP-4 drugs are super imposable. Each DPP-4 drug offers once daily dosing and an identical impact on the key diabetes measures of efficacy, namely fasting blood glucose and hemoglobin A1C. The products also have virtually identical safety profiles. In a properly operating competitive market, the US expansion of the DPP-4 category from a single brand to four fully-interchangeable DPP-4 options should have led to intense price and market share competition.

558. In the oral SGLT-2 segment, following the initial 2013 category approval, three nearly identical drugs, Johnson & Johnson's Invokana/Invokamet (canagliflozin), Astra Zeneca's Farxiga/Xiduo XR (dapaliflozin, FDA approval 2014) and Boehringer Ingelheim/Eli Lilly's Jardiance (empagliflozin, FDA approval 2014) now compete directly. Similar to the DPP-4 segment, the clinical profiles of the three available SGLT-2 drugs are super imposable. Each SGLT-2 drug offers once daily dosing and an identical impact on the key diabetes measures of efficacy, namely fasting blood glucose and hemoglobin A1C. The products also have virtually identical safety profiles. In a properly operating competitive market, three fully-interchangeable SGLT-2 options should provide the PBM Defendants with leverage to garner manufacturer discounts and to prevent severe price inflation. Of note, positive clinical outcome data released in August 2015 for Boehringer Ingeheim/Eli Lilly's Jardiance may provide a utilization boost to the entire SGLT-2 category and to the product specifically.

559. In the US injectable GLP-1 category, available drug options have also expanded considerably since the initial category approval of AstraZeneca's Byetta (exenatide) in 2005, a twice daily subcutaneous injection. After its 2010 launch, Novo Nordisk's once daily GLP-1, Victoza (liraglutide), soon became the market leader. Since 2013, three long-acting weekly GLP-1 therapies have been launched in the US, namely AstraZeneca's Bydureon (exenatide extended-release, FDA approval 2012), Eli Lilly's Trulicity (dulaglutide, FDA approval 2014) and Glaxo's Tanzeum (albiglutide, FDA approval 2014). All of the available GLP-1 products offer similar clinical benefits and side effects. While not super imposable like with oral DPP-4 and

SGLT-2 agents, all of these GLP-1 therapies offer viable clinical profiles sufficient to enable significant category competition in a properly operating competitive market.

560. Recent pricing trends for these three newer brand diabetes segments suggest significant anticompetitive pricing activity and BFSF fraud. Despite a sharp increase in the availability of interchangeable therapeutic options, recent AWP price inflation in the DPP-4, SGLT-2 and GLP-1 categories has been severe and uniform. Since 2011, the AWP cost (at labeled doses) for all DPP-4 drugs has increased almost identically by 60%, from approximately $3,000/patient/year to about $4,800 at present. In the SGLT-2 category, uniform pricing and inflation has also occurred. Despite the arrival of two interchangeable new products in 2014, the AWP cost per year for the category increased by 30% in just the past three years, from about $3,800/patient in 2013 to a uniform $3,937 for all three product in early 2015. Similarly, counter to normal competitive dynamics, uniform AWP price inflation for all the GLP-1 drugs has been significant in recent years despite several new market entrants.

561. Recent pricing trends suggest the potential for significant and accelerating BFSF fraud in the DPP-4, SGLT-2 and GLP-1 diabetes categories. However, the Relator does not allege BFSF fraud related to these newer diabetes segments in this complaint because most products have only been on the US market for a few years. Rather, this complaint focuses on apparent severe fraud in the long-standing insulin segment of the diabetes market. Unlike the other three diabetes brand drug segments, the majority of major insulin products have been available in the US since before the start of Medicare Part D.

562. The insulin category is divided into short-acting and long-acting products. Short-acting products are typically used around meals, while long-acting versions provide baseline insulin levels throughout the day. Within the short-acting sub-segment, newer insulin analogues (Eli Lilly's Humalog, Novo Nordisk's Novolog and Sanofi's Apidra) offer faster onset that long-marketed regular insulins, such as Eli Lilly's Humulin and Novo Nordisk's Novolin. The dominant long-acting insulin product has been Sanofi's Lantus, with recent rising competition from Novo Nordisk's similar product, Levemir. All insulins are administered as

subcutaneous injections and require individualized patient dosing depending upon numerous factors, including age, weight, diet, and insulin sensitivity/resistance.

563. As with the other diabetes brand segments, severe and uniform AWP price inflation of virtually all insulin therapies suggests broad-based BFSF fraud tied to price increases. For instance, despite complete clinical interchangeability, the average AWP cost/patient/year for Eli Lilly's and Novo Nordisk's long-marketed Humulin (FDA approval 1982) and Novolin (FDA approval 1991), respectively, has increased approximately four-fold since the start of Part D. Based upon an estimated average daily dose of 50 units, the average AWP annual cost of therapy for Humulin and Novolin has increased in lock-step from the $660-690 range in 2005 to $2,600 in early 2015. See **Exhibit 14**. Similar vast AWP price inflation has occurred among insulin analogues and long-acting versions. In the long-acting segment, the annual AWP cost/patient/year of both Sanofi's Lantus (FDA approval 2001) and Novo Nordisk's Levemir (FDA approval 2005) has increased nearly four-fold from the $1,600 range in 2005 to the $6,000 range in early 2015. See **Exhibit 13**.

564. While BFSF fraud in the insulin diabetes is likely widespread, this case focuses on the products in which manufacturer-reported product revenues are most disparate from underlying patient utilization trends; namely Sanofi's Lantus and Apidra, as well as Eli Lilly's Humulin. Since the start of 2013, the AWP price of Lantus has increased 68%, while prescription volume as declined 4%. In the Relator's view, this accelerating fraudulent price inflation for Lantus was likely driven by Sanofi's strategic attempts to preserve its US insulin franchise. Eli Lilly/Boehringer plan to launch a biosimilar version of Lantus in the US in 2016. In March 2015, Sanofi launched its new long-acting insulin, Toujeo, in the US. Toujeo is simply a more concentrated version of Lantus, but with extended patent protection. Toujeo was launched at the same price as Lantus, following the vast inflation of the latter. The severe price inflation will serve to maximize Lantus US revenues in the face of accelerating volume erosion. In turn, the revenues generated by Toujeo will also benefit from the fraudulent price increases. The PBM Defendants garner rising fraudulent service fees from both products by cooperating in the pricing scheme.

565. Following vast inflation of brand Lantus, the Relator expects the biosimilar Lantus (US launch expected in late 2016) to be launched at a modest discount to Sanofi's fraudulently-elevated price level, thereby preserving extreme pricing in the key diabetes insulin category. The Relator believes that maintenance of high prices in major brand category prices in the face of isolated competitive threats (as opposed to unavoidable massive price erosion with numerous generics following a traditional drug patent expiration) is a key goal of the systemic pricing scheme between manufacturers and the dominant PBM Defendants.

566. Of note, a similar scenario has already played out in the multiple sclerosis drug category. In April 2015, the first generic version of Teva's daily version of Copaxone was launched at a cost of $63,000 per patient/year, at only a 3% discount to the brand after its years of massive price increases. Prior to the generic arrival, Teva had already switched two-thirds of daily Copaxone patients to its new thrice weekly version in little more than a year, aided by a massive preferential drug coupon program and severe price inflation for the older version. The unprecedented success of this switch program would not have been possible without the cooperation of the PBM Defendants, including considerable service fee payments to them. In a properly-functioning PBM market, the PBM Defendants would be incented to maintain as many patients as possible on the market-share leading daily version of Copaxone in order to maximize the savings potential for clients upon the generic arrival. Also indicative of anticompetitive activity, neither Express Scripts nor CVS Caremark placed any restrictions on brand Copaxone in their recently announced 2016 national formularies.

567. On a smaller scale, Sanofi's Apidra (US approval 2004), its short-acting insulin analague, has exhibited similar trends. Sanofi's reported that US Apidra annual sales increased 119% from approximately $62 million in 2010 to $131 million in 2014, despite only a 23% increase in annual volume over the period.

568. The pricing, volume and reported sales trends for Eli Lilly's Humulin are even more extreme. Between 2010 and 2014, Eli Lilly reported a 51% increase in annual Humulin sales, while annual prescription volume fell by -28% over the period. As such, US Humulin sales would have significantly eroded, if not for severe, anticompetitive price inflation. The Relator estimate that Part D account for 30% of US insulin prescriptions.

569. As noted in the review of the Express Scripts' *Drug Trends Reports*, increased reliance of the Defendant parties on the diabetes category and its individual products for growth has likely increased the magnitude of the BFSF-related pricing fraud. With spending erosion in numerous other major traditional therapeutic categories (high cholesterol, high blood pressure/heart disease, antidepressants, ulcers) following patent expirations, the diabetes category has become, by far, the largest driver of US traditional drug spending. Within Express Scripts' Medicare Part D clientele, diabetes spending per-member-per-year (PMPY) in 2014 was 75% higher than the second largest category, treatments for high cholesterol. Between 2010 and 2014, the diabetes category accounted for two-thirds of Express Scripts' traditional drug spending growth, with more than 80% of the growth due to price increases.

570. Within the diabetes category, Defendant Sanofi's Lantus has been, by far, the greatest single driver of diabetes drug spending within Express Scripts' Medicare population. Driven by severe price increases, Lantus became the top-spending single drug of any type in Express Scripts Medicare segment in 2014, while the product was not even in the *"top ten"* as recently as 2012. See **Exhibit 30**. Sanofi's heavy reliance on Lantus has likely contributed to the product's astounding price inflation. Lantus accounted for 45% of Sanofi's US sales in 2014 and more of its growth and profits.

Pfizer Products:

571. In addition to the above three major therapeutic categories, the Relator also alleges significant fraud related to BFSFs for several of Pfizer's major US drug products. Due to a wide array of patent expirations, Pfizer has experienced severe US sales erosion for many of its prior leading brand drugs over the past decade, including Lipitor (cholesterol-lowering), Zoloft (antidepressant), Zyvox (antibiotic), Zyrtec (antihistamine), etc. In addition, many of Pfizer's remaining US brand drugs have faced eroding usage trends due to both clinical and competitive factors. The Pfizer products targeted in this complaint are Lyrica, Premarin, Celebrex, Viagra, Pristiq, Chantix and Relpax. Except for Lyrica, the US prescription volume for all these products has eroded considerably in recent years. However, counter to sluggish and/or falling prescription

volume, Pfizer has reported strong US sales growth for all these brand products in recent years, driven by severe price increases. In aggregate, these seven products accounted for $7.4 billion or 39% of Pfizer's US sales of $19.1 billion in 2014.

572. In Part D, the Relator alleges that the majority of this price inflation and related sales has been enabled by fraudulent BFSF arrangements between Pfizer and the PBM Defendants. Of note, all these targeted Pfizer drugs are traditional oral therapies, not specialty drugs. As traditional oral drugs, legitimate PBM Defendant services are likely very modest for each of these products, thereby escalating the fraud risk associated with *"percent of revenue"* BFSF contracts tied to severe price increases. Due to cumulative impact of severe price increases, the magnitude of BFSF fraud and related fraudulent US product sales for each targeted product has increased with each year of the Part D program.

573. Pfizer's Lyrica (pregabalin) received FDA approval for three indications in September 2004, namely neuropathic pain associated with diabetic peripheral neuropathy (DPN), postherpetic neuralgia (PHN) and as adjunctive therapy in the treatment of partial seizures in adults. Lyrica later received approval for treating fibromyalgia in June 2007. Lyrica is structurally-related to gabapentin, a widely-used generic drug; both share a similar mechanism of action. Lyrica offers a modest improvement in dosing (2-3 times a day vs. 3-4 times a day for gabapentin) and a greater number of approved indications. While gabapentin is widely-used off-label for a wide variety of neurologic pain syndromes, the molecule (former brand, Pfizer's Neurontin) was only FDA-approved for seizures and PHN. Within the medical community, many physicians consider Lyrica to offer relatively minor clinical advantages compared to generic gabapentin, especially considering the extreme cost differential. The availability of other therapies for neurologic pain has also negatively impacted Lyrica's patient use.

574. With these market dynamics, US prescription trends for Lyrica have been sluggish in recent years. According to IMS, total prescriptions growth for Lyrica has increase an average of 1% per year between 2010 and 2014. See **Exhibit 20**. The number of annual US Lyrica prescriptions in 2014 is only 4% higher

than the level in 2010. Driven by severe price increases, Pfizer has reported robust US Lyrica sales growth in recent years, with reported annual US sales rising 62% from $1.4 billion in 2010 to $2.3 billion in 2014. Virtually all of this revenue growth can be attributed to price increases. According to Red Book, the AWP price for a 150mg pill of Lyrica has tripled since 2007 from $2.31 to $6.94 as of June 2015. See **Exhibit 20**. The AWP unit price of Lyrica has increased by a factor of 2.5 from $2.97 just since the start of 2010, with Pfizer instituting 19% price increases each of the past four years, including 2015. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per Lyrica-treated patient has increased 57% from $1,800 in 2010 to $2,800 in 2014. See **Exhibit 20**. The Relator alleges that all of Lyrica's price-driven US sales growth has been enabled by fraudulent BFSF arrangements with the PBM Defendants.

575. Pfizer's Premarin (conjugated estrogen) is one of the longest-marketed US brand products, available since 1942. The product is FDA-approved for the treatment of vasomotor symptoms due to menopause, vaginal atrophy and the prevention of osteoporosis. Due to its complex formulation derived from horse urine, AB-rated, fully-substitutable generic versions of Premarin have yet to reach the US market despite numerous development attempts. In 1995, the combination hormonal product, Prempro (conjugated estrogen/medroxyprogesterone) was approved in the US. The progesterone component of Prempro decreases the uterine cancer risk associated with unopposed estrogen therapy. Over the past decade the use of Premarin/Prempro, and the many other estrogen formulations available in the US, has declined sharply due to health and safety concerns. All estrogens now carry a FDA *"black box"* safety warning regarding cancer and cardiovascular risks.

576. According to IMS, combined US prescriptions for all Premarin/Prempro formulations has declined an average of 13% per year from 2010 through 2014. In 2014, the annual number of US Premarin franchise prescriptions was 41% less than the level in 2010. See **Exhibit 20**. However, despite this sharp erosion in usage, Pfizer has reported a modest increase in annual US Premarin sales over this timeframe. Pfizer reported US Premarin sales of $949 million 2010, rising to $992 million in 2014. According to Red Book, the AWP price of all Premarin formulations has increased more than three-fold from $1.40 per pill in early 2006 to

$4.35 in early 2015. Just since early 2010, the unit price has more than doubled from $1.94. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Premarin-treated patient increased 78% from $892 in 2010 to $1,590 in 2014. The Relator alleges that all of Premarin's price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. US Premarin sales would have eroded significantly without BFSF-related pricing fraud.

577. Pfizer's Celebrex (celecoxib) was initially approved by the FDA as an anti-inflammatory/pain therapy in 1998. The product is currently approved for the treatment of osteoarthritis, acute pain, rheumatoid arthritis, dysmenorrhea and ankylosing spondylitis. Unlike the anti-TNF drugs, Celebrex is primarily for symptomatic benefit and is not *"disease-modifying"*. In its early years of launch, Celebrex's US uptake was robust. However, over the past decade, use of the drug has eroded considerably due to rising safety concerns. The product's label now includes an FDA *"black box"* warning regarding increased cardiac events (including strokes and heart attacks) and gastrointestinal events (bleeding, ulcers and perforation).

578. According to IMS, the US prescription volume for Celebrex has declined an average of 5% per year between 2010 and 2013. The total annual US prescriptions written for Celebrex were 20% lower in 2014 compared to 2010. Despite this erosion, Pfizer reported average US sales growth of 7% per year between 2010 and 2013. In 2014, Celebrex reported US sales and prescriptions were in-line with each other, with a 10% and 9% decline for 2014. Overall, Pfizer reported a 10% increase in annual US Celebrex sales between 2010 and 2014, from $1.58 billion to $1.74 billion, despite significant erosion in patient usage. According to Red Book, the AWP price of Celebrex increased more than three-fold from $3.34 per 200 mg pill in early 2006 to $10.09 in early 2015. Just since early 2010, the unit price has more than doubled from $1.94. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Celebrex-treated patient increased 38% from $1,811 in 2010 to $2,502 in 2014. The Relator alleges that all of Celebrex's price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. US Celebrex sales would have eroded significantly without BFSF-related pricing fraud.

579. Pfizer's Pristiq (desvenlafaxine) was FDA-approved for the treatment of depression in 2008. Pristiq is a serontonin and norepinephrine reuptake inhibitor (SNRI). The usage of Pristiq has been moderate since launch due to availability of a wide array of generic antidepressants offering similar clinical profiles. Former similar major US antidepressant brands that are now generically-available include Prozac, Zoloft, Paxil, Lexapro, Cymbalta and Effexor.

580. According to IMS, the annual US prescription volume for Pristiq has declined by 22% between 2010 and 2014. Despite this erosion, Pfizer reported a 37% increase in annual US Pristiq sales between 2010 and 2014, entirely driven by severe price inflation. Pfizer reported US Pristiq sales of $553 million in 2014, up from $405 million in 2010. According to Red Book, the AWP price of Pristiq increased about 150% from $4.09 per 50 mg pill in early 2008 to $10.14 in early 2015. Pfizer has instituted 19% AWP price increases for Pristiq each year between 2013 and 2015, with 13-15% annual increases in 2011 and 2012. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Pristiq-treated patient increased 75% from $1,330 in 2010 to $2,329 in 2014. The Relator alleges that all of Pristiq's price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. US Pristiq sales would have eroded significantly without BFSF-related pricing fraud.

581. Pfizer's Relpax (eletriptan) was FDA-approved for the acute treatment of migraines in 2002. Relpax acts as a serotonin receptor agonist. The usage of Relpax has been modest since launch due the availability of numerous other similar serotonin migraine therapies. In more recent years, patient usage of Relpax has eroded due to the availability of generics for the three former market-leading serotonin therapies, Glaxo's Imitrex (sumatriptan, 2009 patent expiry), Merck's Maxalt (rizatriptan, 2013 patent expiry) and Astra Zeneca's Zomig (zolmitriptan, 2013 patent expiry).

582. According to IMS, the annual US prescription volume for Relpax has declined by 18% between 2010 and 2014. Despite this erosion, Pfizer reported a 29% increase in annual US Relpax sales between 2010 and 2014, entirely driven by severe price inflation. Pfizer reported US Relpax sales of $244 million in 2014, up

from $189 million in 2010. According to Red Book, the AWP price of Relpax increased nearly three-fold from $18.32 per 20 mg pill in early 2005 to $45.45 in June 2015. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Relpax-treated patient increased 57% from $1,784 in 2010 to $2,805 in 2014. The Relator alleges that all of Relpax's price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. US Relpax sales would have eroded significantly without BFSF-related pricing fraud.

583. Pfizer's Chantix (varenicline) was FDA-approved as an aid to smoking cessation treatment in 2006. Due to its modest efficacy and safety concerns, use of Chantix has been relatively modest. The FDA label for Chantix includes a *"black box"* safety warning regarding serious neuropsychiatric events, including agitation, depression and suicidal ideation. Chantix competes with numerous other prescription and over-the-counter smoking cessation therapies, including numerous nicotine products.

584. According to IMS, the annual US prescription volume for Chantix has declined by 29% between 2010 and 2014. Despite this erosion, Pfizer reported a 14% increase in annual US Chantix sales between 2010 and 2014, entirely driven by severe price inflation. Pfizer reported US Chantix sales of $377 million in 2014, up from $330 million in 2010. According to Red Book, the AWP price of Chantix increased three-fold from $1.92 per 1 mg tablet in early 2005 to $5.67 in June 2015. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Chantix-treated patient increased 61% from $1,279 in 2010 to $2,064 in 2014. The Relator alleges that all of Chantix's price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. US Chantix sales would have eroded significantly without BFSF-related pricing fraud.

585. Pfizer's Viagra (sildenafil) was FDA-approved for the treatment of erectile dysfunction in 1998. Viagra is a phosphodiesterase-5 (PDE-5) inhibitor. In 2003, two additional PDE-5 drugs, Eli Lilly's Cialis (tadalafil) and Bayer's Levitra were launched in the US. More recently, a fourth PDE-5 drug, Endo Pharmaceutical's

Stendra (avanafil) was approved by the FDA in 2012. Intense competition in this maturing therapeutic category has affected the usage of both Viagra and Cialis.

586. According to IMS, the annual US prescription volume for Pfizer's Viagra has declined by 20% between 2010 and 2014. Despite this erosion, Pfizer reported a 15% increase in annual US Viagra sales between 2010 and 2014, entirely driven by severe price inflation. Pfizer reported US Viagra sales of $1.14 billion in 2014, up from $992 million in 2010.

587. According to Red Book, the AWP price of Viagra increased four-fold from $11.46 per 100 mg tablet in early 2006 to $45.46 in June 2015. See **Exhibit 20**. Based on reported sales and IMS prescription volume, Pfizer net annual revenues per US Viagra-treated patient increased 45% from $1,294 in 2010 to $1,880 in 2014. The Relator alleges that all of Pfizer's Viagra price-driven US sales growth in Part D has been enabled by fraudulent BFSF arrangements with the PBM Defendants. The Relator conservatively estimates that 10% of US Viagra prescriptions are written for Medicare Part D beneficiaries. Use of PDE-5 inhibitors in Medicare Part D is relatively modest because PDE-5 drugs are typically only covered for patients with underlying medical causes leading to erectile dysfunction.

CLAIMS ON BEHALF OF THE UNITED STATES OF AMERICA

COUNT ONE
False Claims Act
31 U.S.C. §§3729(a)(l) and (a)(2)
(Against All Defendants)

588. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

589. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

590. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment or approval, within the meaning of 31 U.S.C. §3729(a)(1).

591. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2).

592. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

593. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

594. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT TWO
False Claims Act
31 U.S.C. §3729(a)(3)
(Against All Defendants)

595. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

596. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

597. By virtue of the acts described above, Defendants conspired with others known and unknown, including without limitation Service Vendors, to defraud the United States by inducing the United States to pay and/or approve false and fraudulent claims, within the meaning of 31 U.S.C. §3729(a)(3). Defendants, moreover, took substantial steps in furtherance of the conspiracy, inter alia, by making false and fraudulent statements and representations, by preparing false and fraudulent records, and/or by failing to disclose material facts.

598. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

599. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every violation of 31 U.S.C. §3729(a)(3) as described herein.

COUNT THREE
Federal False Claims Act
31 U.S.C. §3729(a)(7)
(Against All Defendants)

600. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

601. This is a claim for penalties and treble damages under the Federal False Claims Act.

602. By virtue of the acts described above, including without limitation Defendants' overpayment of BFSFs in lieu of rebates, which would have reduced the ultimate cost reimbursed by the federal government under Medicare Part D, to Service Vendors, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States Government, within the meaning of 31 U.S.C. §3729(a)(7).

603. As a result, money was lost to the United States through the non-payment or non-transmittal of money from foregone discounts and rebates to which the United States was entitled and owed by the Defendants, and other costs were sustained by the United States.

604. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

605. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every false record or statement knowingly made, used, or caused to be made or used to conceal, avoid, or decrease an obligation to pay or transmit money or property to the United States.

COUNT FOUR
Federal False Claims Act
31 U.S.C. §§3729(a)(l) and (a)(2)
(Against All Defendants)

606. Plaintiff repeats and alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

607. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

608. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to officers, employees or agents of the United States Government for payment and/or approval, within the meaning of 31 U.S.C. §3729(a)(1) by paying BFSFs as illegal remuneration to Service Vendors (primarily PBMs and their specialty pharmacy subsidiaries in Medicare Part D) in order to induce purchase of Defendants' MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

609. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false or fraudulent records and statements, and omitted material facts, to get false or fraudulent claims paid and/or approved by the United States Government, within the meaning of 31 U.S.C. §3729(a)(2) by paying BFSFs as illegal remuneration to induce Service Vendors to purchase MS drugs which were then reimbursed by the federal government under Medicare Part D in violation of the Anti-Kickback Statute.

610. The United States, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.

611. By reason of the Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

612. Additionally, the United States is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants arising from their unlawful conduct as described herein.

COUNT FIVE
California False Claims Act Cal Gov't. Code §12651(a)(7)
(Against All Defendants)

613. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

614. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment

by the State of California via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

615. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of California, within the meaning of Cal Gov't. Code §12651(a)(7). The State of California has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIX
Colorado Medicaid False Claims Act
Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310
(Against All Defendants)

616. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

617. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Colorado via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

618. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Colorado. The State of Colorado has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVEN
Connecticut False Claims Act
Conn. Gen. Stat. § 17b-301b(a)(7)
(Against All Defendants)

619. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

620. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Connecticut via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

621. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Connecticut, within the meaning of Conn. Gen. Stat. § 17b-301b(a)(7). The State of Connecticut has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHT
Delaware False Claims and Reporting Act
6 Del Code §1201(a)(7)
(Against All Defendants)

622. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

623. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service*

Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Delaware via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

624. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Delaware, within the meaning of 6 Del. Code §1201(a)(7). The State of Delaware has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINE
Florida False Claims Act
Fla. Stat. Ann. §68.082(2)(g)
(Against All Defendants)

625. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

626. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Florida via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

627. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Florida, within the meaning of Fla. Stat. Ann. §68.082(2)(g). The State of

Florida has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TEN
Georgia False Medicaid Claims Act
Ga. Code Ann. §49-4-168.1(7)(Against All Defendants)

628. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

629. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Georgia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

630. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Georgia, within the meaning of Ga. Code Ann. §49-4-168.1 (7). The State of Georgia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT ELEVEN
Hawaii False Claims Act
Haw. Rev. Stat. §661-21(a)(7)
(Against All Defendants)

631. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

632. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Hawaii via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

633. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Hawaii within the meaning of Haw. Rev. Stat. §661-2l(a)(7). The State of Hawaii has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWELVE
Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. §175/3(a)(7)
(Against All Defendants)

634. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

635. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Illinois via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

636. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Illinois, within the meaning of 740 Ill. Comp. Stat. §175/3(a)(7). The State of Illinois has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTEEN
Indiana False Claims and Whistleblower Protection Act
IC 5-11-5.5-2(b)(6)
(Against All Defendants)

637. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

638. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

639. By vi1iue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Indiana, within the meaning of IC 5-11-5.5-2(b)(6). The State of Indiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FOURTEEN
Iowa False Claims Act
Iowa Code §§ 685.1 through 685.7
(Against All Defendants)

640. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

641. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Indiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

642. By vi1iue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Iowa. The State of Iowa has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT FIFTEEN
Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat.§ 46:438.3(C)
(Against All Defendants)

643. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

644. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and

claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Louisiana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

645. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Louisiana, within the meaning of La. Rev. Stat. § 46:438.3(C). The State of Louisiana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SIXTEEN
Maryland False Health Claims Law
Health-Gen. & 2-602 (a) (1), (2)
(Against All Defendants)

646. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

647. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Maryland via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

648. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Maryland, within the meaning of MD Code Ann., Health-Gen. § 2-

602 (a) (1), (2). The State of Maryland has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT SEVENTEEN
Massachusetts False Claims Law
Mass. Gen. Laws ch. 12 §5B(8)
(Against All Defendants)

649. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

650. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Massachusetts via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

651. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Massachusetts, within the meaning of Mass. Gen. Laws ch. 12 §5B(8). The Commonwealth of Massachusetts has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT EIGHTEEN
Michigan Medicaid False Claims Act
§400.607(3)
(Against All Defendants)

652. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

653. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Michigan via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

654. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Michigan, within the meaning of §400.607(3). The State of Michigan has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT NINETEEN
Minnesota False Claims Act
Minn. Stat. §§ 15C.01 through 15C.16
(Against All Defendants)

655. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

656. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Minnesota via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

657. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota. The State of Minnesota has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY
Montana False Claims Act
Mont. Code Ann. 17-8-403(1)(g)
(Against All Defendants)

658. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

659. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Montana via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

660. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Montana, within the meaning of Mont. Code Ann. 17-8-403(1)(g). The State of Montana has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-ONE
Nevada Submission of False Claims to State or Local Government Act
Nev. Rev. Stat. Ann. §357.040(1)(g)
(Against All Defendants)

661. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Nevada via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

662. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Nevada, within the meaning of Nev. Rev. Stat. Ann. §357.040(l)(g). The State of Nevada has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-TWO
New Hampshire False Claims ActN.H. Rev. Stat. Ann. §167:61-b(l)(e)
(Against All Defendants)

663. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

664. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment

by the State of New Hampshire via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

665. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Hampshire, within the meaning of N.H. Rev. Stat. Ann. §167:61-b(I)(e). The State of New Hampshire has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-THREE
New Jersey False Claims Act
N.J. Stat. §2A:32C-3(g)
(Against All Defendants)

666. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

667. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Jersey via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

668. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Jersey, within the meaning of N.J. Stat. §2A:32C-3(g). The State of New Jersey has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FOUR
New Mexico Medicaid False Claims Act
N.M. Stat. Ann.§ 27-14-3(a)(7)
(Against All Defendants)

669. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

670. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New Mexico via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

671. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New Mexico, within the meaning of N.M. Stat. Ann. § 27-14-3(a)(7). The State of New Mexico has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-FIVE
New York False Claims Act
NY CLS St. Fin. §189(g)
(Against All Defendants)

672. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

673. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service*

Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of New York via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

674. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of New York, within the meaning of NY CLS St. Fin. §189(g). The State of New York has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENT-SIX
North Carolina False Claims Act
2009-554 N.C. Sess. Laws §1-607(a)(7)
(Against All Defendants)

675. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

676. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of North Carolina via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

677. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of North Carolina, within the meaning of 2009-554 N.C.

Sess. Laws §1-607(a)(7). The State of North Carolina has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-SEVEN
Oklahoma Medicaid False Claims Act
Okla. Stat. tit. 63, §5053.1B (7)
(Against All Defendants)

678. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

679. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Oklahoma via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

680. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Oklahoma, within the meaning of Okla. Stat. tit. 63, §5053.1B (7). The State of Oklahoma has thereby suffered actual damages and is entitled to recover treble Oklahoma damages and a civil penalty for each false claim.

COUNT TWENTY-EIGHT
Rhode Island State False Claims Act
R.I. Gen. Laws §9-1.1-3(7)
(Against All Defendants)

681. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

682. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Rhode Island via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

683. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Rhode Island, within the meaning of R.I. Gen. Laws §9-1.1-3(7). The State of Rhode Island has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT TWENTY-NINE
Tennessee False Claims Act and Medicaid False Claims Act
Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-181(a)(l)(D)
(Against All Defendants)

684. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

685. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Tennessee via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

686. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Tennessee, within the meaning of Tenn. Code Ann. §§ 4-18-103(a)(7) and 71-5-18l(a)(l)(D). The State of Tennessee has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY
Texas Medicaid Fraud Prevention Act
Tex. Hum. Res. Code Ann. §36.002(12)
(Against All Defendants)

687. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

688. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Texas via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

689. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Texas, within the meaning of Tex. Hum. Res. Code Ann. §36.002(12). The State of Texas has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-ONE
Virginia Fraud Against Taxpayers Act
Va. Code Ann. §8.01-216.3(a)(7)
(Against All Defendants)

690. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

691. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Virginia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

692. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth of Virginia, within the meaning of Va. Code Ann. §8.01-216.3(a)(7). The Commonwealth of Virginia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-TWO
Washington Medicaid Fraud False Claims Act
Wash. Sess. Laws, Laws of 2012
Ch. 241 §§ 201 through 214
(Against All Defendants)

693. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

694. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service*

Fees" (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Washington via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

695. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Washington. The State of Washington has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-THREE
Wisconsin False Claims For Medical Assistance Act
Wis. Stat. §20.931(2)(g)
(Against All Defendants)

696. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

697. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *" Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the State of Wisconsin via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

698. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Wisconsin, within the meaning of Wis. Stat. §20.931(2)(g). The State of

Wisconsin has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-FOUR
District of Columbia False Claims Act D.C. Code Ann. §2-308.14(a)(7)
(Against All Defendants)

699. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

700. During the Relevant Time Period, the Manufacturer Defendants and the PBM Defendants were aware of their obligations to make and to use truthful records or statements regarding the *"Bona fide Service Fees"* (BFSFs) and Prescription Drug Event (PDE) disclosures and submissions to CMS as conditions and claims for payment in the Medicare Part D program. Intentional failure to do so led to fraudulent overpayment by the District of Columbia via Federally-mandated, non-recourse *"Clawback"* payments for Manufacturer Defendants multiple sclerosis (MS) drug costs in the Medicare Part D program.

701. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the District of Columbia, within the meaning of D.C. Code Ann. §2-308.14(a)(7). The District of Columbia has thereby suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT THIRTY-FIVE
Unjust Enrichment

702. Relator repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

703. By virtue of their conduct, Defendants have been unjustly enriched at the expense of the United States. By obtaining money as a result of their violations of federal law, Defendants were unjustly enriched, and are liable to account and pay such amounts to be determined at trial.

704. By this claim, Relator demands a full accounting of all BFSFs (and interest thereon) incurred and/or paid by the Manufacturer Defendants to the PBM Defendants for services and disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States.

COUNT THIRTY-SIX
Common Law Fraud

705. Plaintiff repeats and realleges each and every allegation contained in the paragraphs above as though fully set forth herein.

706. Manufacturer Defendants made or caused to be made material and false representations concerning the calculation, for which they are responsible, of the BFSFs that were paid to the PBM Defendants for services that CMS requires be provided at FMV, which representations were made by Service Vendors for Services that CMS requires be provided at FMV, with knowledge of their falsity or with reckless disregard for the truth. The PBM Defendants then knowingly submitted false claims for payment to the United States to act upon those misrepresentations to the United States' detriment. The United States acted in justifiable reliance upon both the Manufacturer Defendants and the PBM Defendants misrepresentations by making payments on the false claims.

707. Had the Manufacturer Defendants and the PBM Defendants made truthful statements, the United States would not have made payments for excessive prices for the Manufacturer Defendants' multiple sclerosis drugs in Medicare Part D.

708. As a direct and proximate cause of Defendants' conduct, the United States has been damaged in an amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, the Relator acting on behalf of and in the name of the United States of America, and on his own behalf, demands and prays that judgment be entered as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.*, and the Anti-Kickback Statute as set forth above;

B. That this Court enter judgment in favor of the United States against the Defendants jointly and severally in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not Eleven Thousand Dollars ($11,000) for each false claim;

C. In favor of the United States against the Defendants for disgorgement of the profits earned by Defendants as a result of their illegal schemes;

D. In favor of the Relator for the maximum amount allowed as a Relator's share pursuant to 31 U.S.C. § 3730(d) and in favor of the Relator against Defendants for reasonable expenses, attorneys' fees and costs incurred by the Relator;

E. In favor of the Relator and the United States and against the Defendants for all costs of this action;

F. In favor of the Relator and the United States and against the Defendants for such other and further relief as this Court deems to be just and equitable.

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Cal. Govt. Code §1651(a);

H. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a

civil penalty of $10,000 for each violation of Colo. Rev. Stat. §§ 25.5-4-303.5 through 25.5-4-310;

I. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Conn. Gen. Stat. § 17b-301b;

J. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 6 Del. C. §1201(a);

K. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Fla. Stat. Ann. §68.082(2);

L. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Ga. Code Am1. §49-4-168.1.

M. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. §661-2l(a);

N. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of 740 Ill. Comp. Stat. §175/3(a);

O. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil penalty of at least $5,000 for each violation of IC 5-11-55;

P. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil penalty of at least $10,000 for each violation of Iowa Code §§ 685.1 through 685.7;

R. That this Court enter judgment against Defendants in an amount equal to three times

the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of La. Rev. Stat. §437 et. seq.;

S. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MD Code Ann., Health-Gen. § 2-602 (a) (1). (2);

T. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12 §5B;

U. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of MI Public Act 337;

V. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Minn. Stat. §§ 15C.01 through 15C.16;

W. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendants ' actions, plus a civil penalty of $10,000 for each violation of Mont. Stat. Ann. 17-8-401;

X. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §357.040(1);

Y. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendants' actions, plus civil penalties for each violation of N. H. Rev. Stat. Ann. §167:61-b(l);

Z. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of N.J. Stat. §2A:32C-3;

AA. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of N.M. Stat. Ann. §27-2F-4;

BB. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of New York has sustained because of Defendants' actions, plus a civil penalty of $12,000 for each violation of NY CLS St. Fin. §189;

CC. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of North Carolina has sustained because of Defendants' actions, plus a civil penalty or $11,000 for each violation of 2009-554 N.C. Sess. Laws §1- 607(a);

DD. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Okla. Stat. tit. 63, §5053.1B;

EE. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of R.I. Gen. Laws §9-1.1-3;

FF. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. §§4-18-103(a) and 71-5-182(a)(l);

GG. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §36.002;

HH. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each violation of Va. Code Ann. §8.01-216.3(a);

II. T hat this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Wisconsin has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wis. Stat. §20.931(2);

JJ. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Washington has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of Wash. Sess. Laws, Laws of 2012, Ch. 241 §§ 201 through 214;

KK. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. §2-308.14(a);

LL. That Relator be awarded the maximum amount allowed pursuant to§3730(d) of the False Claims Act, and the equivalent provisions of the state statutes set forth above;

MM. That Relator be awarded all costs of this action, including attorneys' fees and expenses; &

NN. That Relator recovers such other relief as the Court deems just and proper.

JURY DEMAND

445. Plaintiff/Relator demands a trial by jury on all counts.

Dated: October 6, 2015

Respectfully Submitted,

RELATOR John R. Borzilleri, M.D.
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Exhibit 6

US Anti-TNF Biologic Therapies

Average Wholesale Price (AWP) Trends

	Humira	Enbrel	Cimzia	Simponi
Company/Year of US Launch:	AbbVie (2002)	Amgen (1998)	UCG Group (2008)	Johnson & Johnson (2009)
Maintenance Dosage:	40 mg every other week	50 mg once weekly	200 mg every four weeks	50 mg once a month
	Annual AWP Price Increases (%)			
2004	4.9%	0.0%	-	-
2005	4.3%	4.3%	-	-
2006	4.9%	4.9%	-	-
2007	4.9%	4.9%	-	-
2008	9.8%	9.8%	4.9%	-
2009	4.9%	4.9%	5.9%	4.9%
2010	9.8%	9.8%	2.0%	4.8%
2011	6.9%	5.9%	9.9%	11.8%
2012	13.8%	13.8%	17.9%	13.8%
2013	20.7%	20.7%	19.0%	13.8%
2014	15.8%	21.7%	9.9%	16.8%
YTD Sept 2015	17.8%	17.8%	9.9%	16.8%
Cumulative Change 2008-2015	99.5%	104.4%	79.4%	82.7%
	Annual US Cost Per Patient ($AWP)			
2004	$16,563	$16,901	-	-
2005	$17,277	$17,629	-	-
2006	$20,920	$18,493	-	-
2007	$19,011	$19,399	-	-
2008	$20,920	$21,347	$19,874	-
2009	$21,945	$22,820	$21,062	$23,791
2010	$24,149	$25,111	$22,978	$24,933
2011	$25,815	$26,592	$25,309	$27,960
2012	$29,500	$30,389	$30,301	$31,951
2013	$36,038	$34,728	$36,284	$36,513
2014	$41,956	$42,820	$39,876	$42,896
YTD Sept 2015	$49,753	$49,762	$43,824	$50,396
Cumulative Change 2008-2015	$28,833	$28,415	$23,949	$26,604

Source: Redbook Online/Truven Health Analytics Inc.

Exhibit 7

US Anti-TNF Market

Part D Direct BFSF Payment Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corporate-Reported US Sales ($mil)											
Humira (AbbVie)[1]	$560	$1,200	$1,600	$2,200	$2,520	$2,872	$3,427	$4,377	$5,236	$6,524	1065%
Enbrel (Amgen)	2,470	2,736	3,052	3,389	3,283	3,304	3,458	3,967	4,256	4,404	78%
Cimzia (UCB)	-	-	-	11	101	193	235	292	404	544	-
Simponi (JNJ)	-	-	-	12	97	220	314	412	503	667	-
Combined US Sales ($mil)	$3,030	$3,936	$4,652	$5,611	$6,001	$6,589	$7,434	$9,048	$10,399	$12,139	301%
Growth	-	30%	18%	21%	7%	10%	13%	22%	15%	17%	
Price Increases as % of US Growth	-	36%	3%	54%	83%	89%	59%	72%	47%	70%	67%
Manufacturer US Revenues/Patient ($)											
Humira (AbbVie)	$17,277	$20,920	$19,011	$20,920	$21,945	$24,580	$26,687	$30,941	$33,098	$37,394	116%
Enbrel (Amgen)	17,629	18,493	19,399	21,347	22,820	24,103	25,568	29,151	30,400	31,640	79%
Cimzia (UCB)	-	-	-	19,874	21,062	22,822	22,730	26,243	32,141	41,791	-
Simponi (JNJ)	-	-	-	-	23,791	27,586	29,484	31,721	34,153	43,335	-
Average Price ($)	$17,453	$19,707	$19,205	$20,714	$22,405	$24,773	$26,117	$29,514	$32,448	$38,540	121%
Estimated Annual US-Treated Patients											
Humira (AbbVie)	32,414	57,361	84,160	105,162	114,832	116,843	128,416	141,464	158,197	174,469	438%
Enbrel (Amgen)	140,108	147,946	157,325	158,756	143,865	137,076	135,249	136,084	139,998	139,192	-1%
Cimzia (UCB)	-	-	-	535	4,786	8,457	10,339	11,127	12,570	13,017	-
Simponi (JNJ)	-	-	-	-	4,093	7,967	10,655	13,003	14,737	15,391	-
Combined US-Treated Patients	172,522	205,307	241,485	264,453	267,575	270,343	284,658	301,679	325,501	342,069	98%
Growth	-	19%	18%	10%	1%	1%	5%	6%	8%	5%	
Estimated Actual BFSFs (4% rate)											
Humira (AbbVie)	$22	$48	$64	$88	$101	$115	$137	$175	$209	$261	1065%
Enbrel (Amgen)	99	109	122	136	131	132	138	159	170	176	78%
Cimzia (UCB)	-	-	-	0.4	4	8	9	12	16	22	-
Simponi (JNJ)	-	-	-	0.5	4	9	13	16	20	27	-
Combined Actual BFSFs ($mil)	$121	$157	$186	$224	$240	$264	$297	$362	$416	$486	301%
Estimated Actual BFSFs/Patient ($)					-	-	-	-	-	-	-
Humira (AbbVie)	$691	$837	$760	$837	$878	$983	$1,067	$1,238	$1,324	$1,496	116%
Enbrel (Amgen)	705	740	776	854	913	964	1,023	1,166	1,216	1,266	79%
Cimzia (UCB)	-	-	-	795	842	913	909	1,050	1,286	1,672	-
Simponi (JNJ)	-	-	-	-	952	1,103	1,179	1,269	1,366	1,733	-
Average Actual BFSFs/Patient ($)	$703	$767	$771	$849	$897	$975	$1,045	$1,200	$1,278	$1,419	102%

Exhibit 7 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Estimated Annual BFSFs w/o Price Increases (4% rate)											
Humira (AbbVie)	$22	$40	$58	$73	$79	$81	$89	$98	$109	$121	438%
Enbrel (Amgen)	99	104	111	112	101	97	95	96	99	98	-1%
Cimzia (UCB)	-	-	-	0	4	7	8	9	10	10	-
Simponi (JNJ)	-	-	-	-	4	8	10	12	14	15	-
Combined BFSFs w/o Price Increases ($mil)	$121	$144	$169	$185	$189	$192	$202	$215	$232	$244	101%
Estimated Part D Prescription Share (%)	-	30%	30%	30%	30%	30%	30%	30%	30%	30%	
Estimated Part D Fraudulent BFSFs ($, 4% rate)											-
Humira (AbbVie)	-	$3	$2	$5	$6	$10	$15	$23	$30	$42	-
Enbrel (Amgen)	-	2	3	7	9	11	13	19	21	23	-
Cimzia (UCB)	-	-	-	-	0.1	0.3	0.4	1	2	3	-
Simponi (JNJ)	-	-	-	-	-	0.4	1	1	2	4	-
Combined Fraudulent Part D BFSFs ($mil)	-	$4	$5	$12	$15	$22	$28	$44	$55	$73	-
Cumulative Part D Fraudulent BFSFs ($, 4% rate)											-
Humira (AbbVie)	-	$3	$4	$9	$15	$26	$40	$63	$93	$135	-
Enbrel (Amgen)	-	2	5	12	21	32	44	63	85	108	-
Cimzia (UCB)	-	-	-	-	0.2	1	1	2	4	7	-
Simponi (JNJ)	-	-	-	-	-	1	2	3	5	9	-
Cumulative Fraudulent Part D BFSFs ($mil)	-	$4	$9	$21	$36	$59	$87	$131	$187	$259	-

[1] Estimated 2005 Humira sales at 40% of reported $1.4 billion in global sales.

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 8

US Anti-TNF Market

Part D Sales Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corporate-Reported US Sales ($mil)											
Humira (AbbVie)[1]	$560	$1,200	$1,600	$2,200	$2,520	$2,872	$3,427	$4,377	$5,236	$6,524	1065%
Enbrel (Amgen)	2,470	2,736	3,052	3,389	3,283	3,304	3,458	3,967	4,256	4,404	78%
Cimzia (UCB)	-	-	-	11	101	193	235	292	404	544	-
Simponi (JNJ)	-	-	-	12	97	220	314	412	503	667	-
Combined US Sales ($mil)	$3,030	$3,936	$4,652	$5,611	$6,001	$6,589	$7,434	$9,048	$10,399	$12,139	301%
Growth	-	30%	18%	21%	7%	10%	13%	22%	15%	17%	
Percent of US Sales Due to Price Increases					-	-	-	-	-	-	-
Humira (AbbVie)	-	33%	-	33%	37%	87%	49%	63%	40%	58%	59%
Enbrel (Amgen)	-	48%	45%	92%	>>100%	>>100%	129%	96%	61%	117%	101%
Cimzia (UCB)	-	-	-	-	6%	16%	-2%	69%	66%	90%	53%
Simponi (JNJ)	-	-	-	-	-	25%	21%	30%	39%	86%	53%
Total US Anti-TNF Market	-	36%	3%	54%	83%	89%	59%	72%	47%	70%	67%
Manufacturer US Revenues/Patient ($)											
Humira (AbbVie)	$17,277	$20,920	$19,011	$20,920	$21,945	$24,580	$26,687	$30,941	$33,098	$37,394	116%
Enbrel (Amgen)	17,629	18,493	19,399	21,347	22,820	24,103	25,568	29,151	30,400	31,640	79%
Cimzia (UCB)	-	-	-	19,874	21,062	22,822	22,730	26,243	32,141	41,791	110%
Simponi (JNJ)	-	-	-	-	23,791	27,586	29,484	31,721	34,153	43,335	82%
Average Price ($)	$17,453	$19,707	$19,205	$20,714	$22,405	$24,773	$26,117	$29,514	$32,448	$38,540	121%
Annual US Sales at 2005 Prices ($mil)											
Humira (AbbVie)	$560	$991	$1,454	$1,817	$1,984	$2,019	$2,219	$2,444	$2,733	$3,014	-
Enbrel (Amgen)	2,470	2,608	2,774	2,799	2,536	2,417	2,384	2,399	2,468	2,454	-
Cimzia (UCB)	-	-	-	12	95	168	205	221	250	259	-
Simponi (JNJ)	-	-	-	-	97	190	253	309	351	366	-
Combined US Sales ($mil)	$3,030	$3,599	$4,228	$4,628	$4,713	$4,793	$5,062	$5,374	$5,802	$6,093	-

Exhibit 8 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Annual US Sales due to Price Increases ($mil)											
Humira (AbbVie)	-	$209	$146	$383	$536	$853	$1,208	$1,933	$2,503	$3,510	-
Enbrel (Amgen)	-	128	278	590	747	887	1,074	1,568	1,788	1,950	-
Cimzia (UCB)	-	-	-	-	6	25	30	71	154	285	-
Simponi (JNJ)	-	-	-	-	-	30	61	103	153	301	-
Combined US Fraudulent Sales ($mil)	-	$337	$424	$973	$1,289	$1,796	$2,372	$3,675	$4,598	$6,046	-
Growth	-	-	26%	129%	32%	39%	32%	55%	25%	31%	
Est Part D Prescription Share (%)	-	30%	30%	30%	30%	30%	30%	30%	30%	30%	
Part D Sales due to Pricing Fraud ($mil)											
Humira (AbbVie)	-	$63	$44	$115	$161	$256	$363	$580	$751	$1,053	-
Enbrel (Amgen)	-	38	84	177	224	266	322	470	536	585	-
Cimzia (UCB)	-	-	-	-	2	7	9	21	46	86	-
Simponi (JNJ)	-	-	-	-	-	9	18	31	46	90	-
Combined Part D Fraudulent Sales ($mil)	-	$101	$127	$292	$387	$539	$712	$1,102	$1,379	$1,814	-
Growth	-	-	26%	129%	32%	39%	32%	55%	25%	31%	
Cumulative Part D Fraudulent Sales ($mil)											
Humira (AbbVie)	-	$63	$107	$221	$382	$638	$1,001	$1,581	$2,332	$3,385	-
Enbrel (Amgen)	-	38	122	299	523	789	1,111	1,582	2,118	2,703	-
Cimzia (UCB)	-	-	-	-	2	9	18	39	86	171	-
Simponi (JNJ)	-	-	-	-	-	9	27	58	104	194	-
Cumulative Part D Fraudulent Sales ($mil)	-	$101	$228	$520	$907	$1,446	$2,157	$3,260	$4,639	$6,453	-
Growth	-	-	126%	128%	74%	59%	49%	51%	42%	39%	

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 9
US Chronic Myeloid Leukemia Therapies
Average Wholesale Price (AWP) and Annual Patient Cost Trends

	Gleevec	Sprycel	Tasigna
Company/Year of US Launch:	Novartis (2001)	Bristol-Myers (2006)	Novartis (2007)
Maintenance Dosage:	400 mg once daily	100mg once daily	300-400 mg twice daily
	Annual AWP Price Increases (%)		
2005	0.0%	-	-
2006	7.9%	0.0%	-
2007	7.9%	18.2%	-
2008	15.9%	9.9%	9.8%
2009	14.8%	15.0%	14.8%
2010	14.8%	19.8%	9.9%
2011	14.9%	3.1%	3.1%
2012	19.8%	8.8%	4.9%
2013	9.0%	3.0%	3.5%
2014	19.3%	8.8%	9.8%
YTD Sept 2015	19.8%	7.5%	6.0%
Cumulative Change 2008-2015	128.3%	75.9%	61.8%
	Annual US Cost Per Patient ($AWP)		
2005	$35,734	-	-
2006	$38,572	$64,496	-
2007	$41,619	$76,739	-
2008	$48,050	$80,006	$91,395
2009	$55,395	$92,411	$105,420
2010	$66,991	$111,613	$115,856
2011	$77,305	$115,074	$119,448
2012	$93,368	$125,299	$125,300
2013	$101,772	$129,058	$129,686
2014	$122,361	$140,662	$142,707
YTD Sept 2015	$147,788	$151,211	$151,269
Cumulative Change 2008-2015	$99,737	$71,206	$59,874

Source: Redbook Online/Truven Health Analytics Inc.

Exhibit 10
US Chronic Myeloid Leukemia Market
Part D Direct BFSF Payment Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corp-Reported US Sales ($mil)											
Gleevec (Novartis)	$524	$630	$714	$902	$1,088	$1,285	$1,459	$1,698	$1,939	$2,170	314%
Tasigna (Novartis)	-	-	-	30	62	134	255	351	428	540	-
Sprycel (Bristol-Myers)	-	22	58	92	123	188	299	404	541	671	-
Combined US Sales ($mil)	$524	$652	$772	$1,024	$1,273	$1,607	$2,013	$2,453	$2,908	$3,381	545%
Growth	-	24%	18%	33%	24%	26%	25%	22%	19%	16%	
Price Increases as % of US Growth	-	46%	62%	61%	74%	121%	71%	76%	51%	59%	85%
Manufacturer US Revenues/Patient ($)											
Gleevec (Novartis)	$29,659	$32,015	$34,544	$39,882	$45,978	$62,094	$71,362	$84,955	$94,370	$102,543	246%
Tasigna (Novartis)	-	-	-	75,858	87,498	95,629	91,351	93,066	90,058	104,592	38%
Sprycel (Bristol-Myers)	-	64,496	76,739	80,006	92,411	86,133	105,418	110,375	117,394	120,380	87%
Average Price ($)	$29,659	$48,255	$55,641	$65,248	$75,296	$81,285	$89,377	$96,132	$100,607	$109,172	268%
Est Annual US-Treated Patients											
Gleevec (Novartis)	17,668	19,679	20,669	22,617	23,664	20,694	20,445	19,987	20,547	21,162	20%
Tasigna (Novartis)	-	-	-	395	709	1,401	2,791	3,772	4,753	5,163	-
Sprycel (Bristol-Myers)	-	341	756	1,150	1,331	2,183	2,836	3,660	4,608	5,574	-
Combined US-Treated Patients	17,668	20,020	21,425	24,162	25,703	24,278	26,073	27,419	29,908	31,899	81%
Growth	-	13%	7%	13%	6%	-6%	7%	5%	9%	7%	
Est Actual BFSFs (4% rate)											
Gleevec (Novartis)	$21	$25	$29	$36	$44	$51	$58	$68	$78	$87	314%
Tasigna (Novartis)	-	-	-	1	2	5	10	14	17	22	-
Sprycel (Bristol-Myers)	-	1	2	4	5	8	12	16	22	27	-
Combined Actual BFSFs ($mil)	$21	$26	$31	$41	$51	$64	$81	$98	$116	$135	545%
Est Actual BFSFs/Patient ($)					-	-	-	-	-	-	-
Gleevec (Novartis)	$1,186	$1,281	$1,382	$1,595	$1,839	$2,484	$2,854	$3,398	$3,775	$4,102	246%
Tasigna (Novartis)	-	-	-	3,034	3,500	3,825	3,654	3,723	3,602	4,184	-
Sprycel (Bristol-Myers)	-	2,580	3,070	3,200	3,696	3,445	4,217	4,415	4,696	4,815	-
Average Actual BFSFs/Patient ($)	$1,186	$1,303	$1,441	$1,695	$1,981	$2,648	$3,088	$3,579	$3,889	$4,240	257%

Exhibit 10 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Est BFSFs w/o Price Increases (4% rate)											
Gleevec (Novartis)	$21	$23	$25	$27	$28	$25	$24	$24	$24	$25	20%
Tasigna (Novartis)	-	-	-	-	2	4	8	11	14	16	-
Sprycel (Bristol-Myers)	-	1	2	3	3	6	7	9	12	14	-
Total BFSFs w/o Price Increases ($mil)	$21	$24	$26	$30	$34	$34	$40	$45	$51	$55	163%
Est. Part D Prescription Share (%)	-	55%	55%	55%	55%	55%	55%	55%	55%	55%	-
Est Part D Fraudulent BFSFs ($, 4% rate)										-	
Gleevec (Novartis)	-	$1	$2	$5	$8	$15	$19	$24	$29	$34	-
Tasigna (Novartis)	-	-	-	-	0.2	1	1	1	1	3	-
Sprycel (Bristol-Myers)	-	-	0.2	0.4	1	1	3	4	5	7	-
Combined Fraudulent Part D BFSFs ($mil)	-	$1	$2	$5	$9	$16	$22	$29	$36	$44	-
Cumulative Part D Fraudulent BFSFs ($, 4% rate)										-	
Gleevec (Novartis)	-	$1	$3	$8	$17	$32	$50	$75	$104	$138	-
Tasigna (Novartis)	-	-	-	-	0.2	1	2	3	5	8	-
Sprycel (Bristol-Myers)	-	-	0.2	1	1	2	5	9	14	21	-
Cumulative Fraudulent Part D BFSFs ($mil)	-	$1	$3	$9	$18	$35	$57	$87	$123	$167	-

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 11

US Chronic Myeloid Leukemia (CML) Market: 2010-2015

Corporate-Reported US Sales and Prescription Trends

Corporate-Reported US Sales ($mil)	2010	2011	2012	2013	2014	
Gleevec	$1,285	$1,459	$1,698	$1,939	$2,170	
Tasigna	134	255	351	428	540	
Sprycel	188	299	404	541	671	
Total	$1,607	$2,013	$2,453	$2,908	$3,381	
Total US Prescriptions						
Gleevec	248,333	245,339	239,846	246,561	253,942	
Tasigna	16,815	33,497	45,258	57,030	61,955	
Sprycel	26,192	34,036	43,923	55,301	66,888	
Total	291,340	312,872	329,027	358,892	382,785	
Reported US Sales Growth						Change 2010-2014
Gleevec	18%	14%	16%	14%	12%	69%
Tasigna	116%	90%	38%	22%	26%	303%
Sprycel	53%	59%	35%	34%	24%	257%
Total	26%	25%	22%	19%	16%	110%
Total US Prescription Growth						Change 2010-2014
Gleevec	-	-1%	-2%	3%	3%	2%
Tasigna	-	99%	35%	26%	9%	268%
Sprycel	-	30%	29%	26%	21%	155%
Total	-	7%	5%	9%	7%	31%
US Price/Prescription ($)						Change 2010-2014
Gleevec	$5,175	$5,947	$7,080	$7,864	$8,545	$3,371
Tasigna	$7,969	$7,613	$7,756	$7,505	$8,716	747
Sprycel	$7,178	$8,785	$9,198	$9,783	$10,032	2,854
Total	$5,516	$6,434	$7,455	$8,103	$8,833	$6,972
Annual US Cost of Therapy ($)						Change 2010-2014
Gleevec	$62,094	$71,362	$84,955	$94,370	$102,543	$40,449
Tasigna	$95,629	$91,351	$93,066	$90,058	$104,592	8,963
Sprycel	$86,133	$105,418	$110,375	$117,394	$120,380	34,247
Total	$66,191	$77,207	$89,464	$97,233	$105,992	$83,659
US Total Prescriptions Market Share						Change 2010-2014
Gleevec	85%	78%	73%	69%	66%	-19%
Tasigna	6%	11%	14%	16%	16%	10%
Sprycel	9%	11%	13%	15%	17%	8%
Total	100%	100%	100%	100%	100%	0%

Source: Corporate Reports and IMS.

Exhibit 12

US Chronic Myeloid Leukemia Market

Part D Sales Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corporate-Reported US Sales ($mil)											
Gleevec (Novartis)	$524	$630	$714	$902	$1,088	$1,285	$1,459	$1,698	$1,939	$2,170	314%
Tasigna (Novartis)	-	-	-	30	62	134	255	351	428	540	-
Sprycel (Bristol-Myers)	-	22	58	92	123	188	299	404	541	671	-
Combined US Sales ($mil)	$524	$652	$772	$1,024	$1,273	$1,607	$2,013	$2,453	$2,908	$3,381	545%
Growth	-	24%	18%	33%	24%	26%	25%	22%	19%	16%	
Percent of US Sales Due to Price Increases					-	-	-	-	-	-	-
Gleevec (Novartis)	-	44%	62%	64%	78%	169%	109%	114%	80%	75%	94%
Tasigna (Novartis)	-	-	-	-	26%	16%	-10%	7%	-19%	67%	-
Sprycel (Bristol-Myers)	-	-	26%	11%	53%	-21%	49%	17%	24%	13%	28%
Total US Anti-TNF Market	-	46%	62%	61%	74%	121%	71%	76%	51%	59%	85%
Manufacturer US Revenues/Patient ($)											
Gleevec (Novartis)	$29,659	$32,015	$34,544	$39,882	$45,978	$62,094	$71,362	$84,955	$94,370	$102,543	246%
Tasigna (Novartis)	-	-	-	75,858	87,498	95,629	91,351	93,066	90,058	104,592	38%
Sprycel (Bristol-Myers)	-	64,496	76,739	80,006	92,411	86,133	105,418	110,375	117,394	120,380	87%
Average Price ($)	$29,659	$48,255	$55,641	$65,248	$75,296	$81,285	$89,377	$96,132	$100,607	$109,172	268%
Estimated Annual US-Treated Patients[2]											
Gleevec (Novartis)	17,668	19,679	20,669	22,617	23,664	20,694	20,445	19,987	20,547	21,162	20%
Tasigna (Novartis)	-	-	-	395	709	1,401	2,791	3,772	4,753	5,163	-
Sprycel (Bristol-Myers)	-	341	756	1,150	1,331	2,183	2,836	3,660	4,608	5,574	-
Combined US-Treated Patients	17,668	20,020	21,425	24,162	25,703	24,278	26,073	27,419	29,908	31,899	81%
Growth	-	13%	7%	13%	6%	-6%	7%	5%	9%	7%	
Annual US Sales without Price Increases ($mil)											
Gleevec (Novartis)	$524	$584	$613	$671	$702	$614	$606	$593	$609	$628	-
Tasigna (Novartis)	-	-	-	-	54	106	212	286	361	392	-
Sprycel (Bristol-Myers)	-	22	49	74	86	141	183	236	297	359	-
Combined US Sales ($mil)	$524	$606	$662	$745	$841	$861	$1,001	$1,115	$1,267	$1,379	-

Exhibit 12 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Annual US Sales due to Price Increases ($mil)											
Gleevec (Novartis)	-	$46	$101	$231	$386	$671	$853	$1,105	$1,330	$1,542	-
Tasigna (Novartis)	-	-	-	-	8	28	43	65	67	148	-
Sprycel (Bristol-Myers)	-	-	9	18	37	47	116	168	244	312	-
Total US Fraudulent Sales ($mil)	-	$46	$110	$249	$432	$746	$1,012	$1,338	$1,641	$2,002	-
Growth	-	-	138%	126%	73%	73%	36%	32%	23%	22%	
Est. Part D Prescription Share (%)	-	55%	55%	55%	55%	55%	55%	55%	55%	55%	
Part D Sales due to Pricing Fraud ($mil)											
Gleevec (Novartis)	-	$25	$56	$127	$212	$369	$469	$608	$731	$848	-
Tasigna (Novartis)	-	-	-	-	5	15	24	36	37	82	-
Sprycel (Bristol-Myers)	-	-	5	10	20	26	64	92	134	171	-
Combined Part D Fraudulent Sales ($mil)	-	$25	$61	$137	$237	$410	$557	$736	$902	$1,101	-
Growth	-	-	138%	126%	73%	73%	36%	32%	23%	22%	
Cumulative Part D Fraudulent Sales ($mil)											
Gleevec (Novartis)	-	$25	$81	$208	$421	$790	$1,259	$1,867	$2,598	$3,446	-
Tasigna (Novartis)	-	-	-	-	5	20	44	79	116	198	-
Sprycel (Bristol-Myers)	-	-	-	-	-	26	90	182	316	488	-
Cumulative Part D Fraudulent Sales ($mil)	-	$25	$81	$208	$425	$836	$1,392	$2,128	$3,030	$4,132	-
Growth	-	-	218%	157%	104%	97%	67%	53%	42%	36%	

Source: Corporate reports and IMS and Redbook.

Exhibit 13

US Long-Acting Insulin Therapies

Average Wholesale Price (AWP) Trends

	Lantus	Levemir
Company/Year of FDA Approval:	Sanofi (2000)	Novo Nordisk (2005)
Est. Average Daily Dose[1]:	50 units	50 units
Est. Average Annual Dose:	18,250 units	18,250 units
	Annual AWP Price Increases (%)	
2003	13.6%	-
2004	18.0%	-
2005	13.0%	-
2006	6.5%	0.0%
2007	9.7%	3.6%
2008	14.5%	11.9%
2009	6.0%	6.0%
2010	15.0%	15.5%
2011	14.9%	13.0%
2012	14.9%	18.0%
2013	39.7%	22.0%
2014	28.0%	28.0%
YTD Sept 2015	0.0%	8.2%
Cumulative Change 2006-2015	149.2%	126.2%
	Annual US Cost Per Patient ($AWP)	
2003	$978	-
2004	$1,162	-
2005	$1,318	-
2006	$1,405	$1,528
2007	$1,545	$1,582
2008	$1,776	$1,776
2009	$1,883	$1,883
2010	$2,176	$2,206
2011	$2,500	$2,492
2012	$2,886	$2,959
2013	$4,189	$4,189
2014	$5,442	$5,442
YTD Sept 2015	$5,442	$5,891
Cumulative Change 2006-2015	$4,037	$4,364

Source: Redbook Online/Truven Health Analytics Inc.

Exhibit 14
US Short-Acting Regular Insulin Therapies
Average Wholesale Price (AWP) Trends

	Humulin R	Novolin R
Company/Year of FDA Approval:	Eli Lilly (1982)	Novo Nordisk (1991)
Est. Average Daily Dose:	50 units	50 units
Est. Average Annual Dose:	18,250 units	18,250 units
	Annual AWP Price Increases (%)	
2003	5.0%	9.4%
2004	5.0%	5.0%
2005	8.0%	8.0%
2006	9.0%	4.6%
2007	9.2%	9.4%
2008	15.6%	13.8%
2009	6.0%	9.9%
2010	18.0%	30.0%
2011	22.0%	20.0%
2012	16.0%	15.0%
2013	18.7%	18.8%
2014	19.8%	19.8%
YTD Sept 2015	9.9%	9.9%
Cumulative Change 2006-2015	144.2%	151.2%
	Annual US Cost Per Patient ($AWP)	
2003	$534	$557
2004	$561	$585
2005	$606	$631
2006	$660	$660
2007	$723	$723
2008	$840	$818
2009	$890	$899
2010	$1,058	$1,187
2011	$1,428	$1,436
2012	$1,664	$1,660
2013	$1,989	$1,985
2014	$2,402	$2,399
YTD Sept 2015	$2,641	$2,638
Cumulative Change 2006-2015	$1,981	$1,977

Source: Redbook Online/Truven Health Analytics Inc.

Exhibit 15

US Insulin Market

Part D Direct BFSF Payment Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corporate-Reported US Sales ($mil)											
Lantus (Sanofi)	$846	$1,328	$1,740	$2,018	$2,749	$2,838	$3,037	$4,198	$4,946	$5,831	589%
Apidra (Sanofi)	-	-	-	-	78	82	85	99	148	181	-
Humulin (Eli Lilly)	411	368	365	381	402	471	588	592	677	713	-
Combined US Sales ($mil)	$1,257	$1,696	$2,105	$2,399	$3,229	$3,391	$3,709	$4,890	$5,771	$6,724	435%
Growth	-	35%	24%	14%	35%	5%	9%	32%	18%	17%	
Price Increases as % of US Growth	-	54%	59%	113%	33%	261%	53%	93%	91%	80%	86%
Manufacturer US Revenues/Patient ($)											
Lantus (Sanofi)	$1,288	$1,372	$1,505	$1,724	$1,827	$2,101	$2,116	$2,715	$3,100	$3,503	172%
Apidra (Sanofi)	1,695	1,695	1,769	2,113	2,239	2,419	2,165	2,379	2,924	3,566	69%
Humulin (Eli Lilly)	682	744	812	939	995	1,174	1,505	1,857	2,327	2,485	234%
Average Price ($)	$1,222	$1,270	$1,362	$1,592	$1,687	$1,898	$1,928	$2,317	$2,783	$3,185	161%
Estimated Annual US-Treated Patients											
Lantus (Sanofi)	656,662	967,750	1,155,936	1,171,010	1,504,671	1,350,895	1,435,338	1,546,578	1,595,328	1,664,302	153%
Apidra (Sanofi)	-	-	-	-	34,723	34,094	39,036	41,736	50,567	50,697	-
Humulin (Eli Lilly)	602,018	494,753	449,745	405,778	404,418	400,984	390,804	318,787	291,080	286,965	-
Combined US-Treated Patients	1,258,680	1,462,503	1,605,681	1,576,788	1,943,812	1,785,972	1,865,178	1,907,101	1,936,975	2,001,964	59%
Growth	-	16%	10%	-2%	23%	-8%	4%	2%	2%	3%	
Estimated Actual BFSFs (4% rate)											
Lantus (Sanofi)	$34	$53	$70	$81	$110	$114	$121	$168	$198	$233	589%
Apidra (Sanofi)	-	-	-	-	3	3	3	4	6	7	-
Humulin (Eli Lilly)	16	15	15	15	16	19	24	24	27	29	-
Combined Actual BFSFs ($mil)	$50	$68	$84	$96	$129	$136	$148	$196	$231	$269	435%
Estimated Actual BFSFs/Patient ($)					-	-	-	-	-	-	-
Lantus (Sanofi)	$52	$55	$60	$69	$73	$84	$85	$109	$124	$140	172%
Apidra (Sanofi)	-	-	-	-	90	97	87	95	117	143	-
Humulin (Eli Lilly)	27	30	32	38	40	47	60	74	93	99	-
Average Actual BFSFs/Patient ($)	$40	$46	$52	$61	$66	$76	$80	$103	$119	$134	236%

Exhibit 15 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Estimated Annual BFSFs w/o Price Increases (4% rate)											
Lantus (Sanofi)	$34	$50	$60	$60	$78	$70	$74	$80	$82	$86	153%
Apidra (Sanofi)	-	-	-	-	3	3	3	4	4	4	-
Humulin (Eli Lilly)	18	15	13	12	12	12	12	9	9	9	-
Combined BFSFs w/o Price Increases ($mil)	$52	$65	$73	$72	$93	$84	$89	$93	$95	$99	91%
Est. Part D Prescription Share (%)	-	30%	30%	30%	30%	30%	30%	30%	30%	30%	
Estimated Part D Fraudulent BFSFs ($, 4% rate)										-	
Lantus (Sanofi)	-	$1	$3	$6	$10	$13	$14	$26	$35	$44	-
Apidra (Sanofi)	-	-	-	-	0.1	0.1	0.0	0.1	0	1	-
Humulin (Eli Lilly)	-	0.0	0.4	0.9	1	2	4	4	6	6	-
Combined Fraudulent Part D BFSFs ($mil)	-	$1	$3	$7	$11	$15	$18	$31	$41	$51	-
Cumulative Part D Fraudulent BFSFs ($, 4% rate)										-	
Lantus (Sanofi)	-	$1	$4	$10	$20	$33	$47	$74	$108	$153	-
Apidra (Sanofi)	-	-	-	-	0.1	0	0	0	1	2	-
Humulin (Eli Lilly)	-	0	0	1	3	5	8	12	18	24	-
Cumulative Fraudulent Part D BFSFs ($mil)	-	$1	$4	$11	$22	$38	$56	$86	$127	$178	-

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 16
Manufacturer Defendant Insulin Products
Corporate-Reported US Sales and Prescription Trends

	2010	2011	2012	2013	2014	Change 2010-2014
Reported US Sales ($mil)						
Lantus (Sanofi)[1]	$2,838	$3,037	$4,198	$4,946	$5,831	$2,992
Apidra (Sanofi)	82	85	99	148	181	98
Humulin (Eli Lilly)	471	588	592	677	713	242
Total Prescriptions						
Lantus (Sanofi)	16,210,734	17,224,054	18,558,937	19,143,930	19,971,626	3,760,892
Apidra (Sanofi)	409,131	468,436	500,826	606,809	608,367	199,236
Humulin (Eli Lilly)	4,811,802	4,689,645	3,825,449	3,492,961	3,443,574	-1,368,228
Reported US Sales Growth						
Lantus (Sanofi)	-	7%	38%	18%	18%	105%
Apidra (Sanofi)	-	2%	17%	49%	22%	119%
Humulin (Eli Lilly)	-	25%	1%	14%	5%	51%
Reported US Rx Growth						
Lantus (Sanofi)	-	6%	8%	3%	4%	23%
Apidra (Sanofi)	-	14%	7%	21%	0%	49%
Humulin (Eli Lilly)	-	-3%	-18%	-9%	-1%	-28%

[1] At average corporate-reported Euro/$ exchange rates.

Source: Corporate Reports and IMS.

Exhibit 17

US Insulin Market

Part D Sales Fraud Estimates: 2006 to 2014

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Corporate-Reported US Sales ($mil)											
Lantus (Sanofi)	$846	$1,328	$1,740	$2,018	$2,749	$2,838	$3,037	$4,198	$4,946	$5,831	589%
Apidra (Sanofi)	-	-	-	-	78	82	85	99	148	181	132%
Humulin (Eli Lilly)	411	368	365	381	402	471	588	592	677	713	94%
Combined US Sales ($mil)	$1,257	$1,696	$2,105	$2,399	$3,229	$3,391	$3,709	$4,890	$5,771	$6,724	435%
Growth	-	35%	24%	14%	35%	5%	9%	32%	18%	17%	
Percent of US Sales Due to Price Increases					-	-	-	-	-	-	-
Lantus (Sanofi)	-	17%	37%	92%	21%	415%	11%	80%	82%	76%	74%
Apidra (Sanofi)	-	-	-	-	-	130%	-	60%	57%	99%	65%
Humulin (Eli Lilly)	-	-	-	327%	106%	105%	110%	-	160%	127%	145%
Total US Anti-TNF Market	-	54%	59%	113%	33%	261%	53%	93%	91%	80%	86%
Manufacturer US Revenues/Patient ($)											
Lantus (Sanofi)	$1,288	$1,372	$1,505	$1,724	$1,827	$2,101	$2,116	$2,715	$3,100	$3,503	172%
Apidra (Sanofi)	1,695	1,695	1,769	2,113	2,239	2,419	2,165	2,379	2,924	3,566	69%
Humulin (Eli Lilly)	682	744	812	939	995	1,174	1,505	1,857	2,327	2,485	234%
Average Price ($)	$1,222	$1,270	$1,362	$1,592	$1,687	$1,898	$1,928	$2,317	$2,783	$3,185	161%
Estimated Annual US-Treated Patients											
Lantus (Sanofi)	656,662	967,750	1,155,936	1,171,010	1,504,671	1,350,895	1,435,338	1,546,578	1,595,328	1,664,302	153%
Apidra (Sanofi)	-	-	-	-	34,723	34,094	39,036	41,736	50,567	50,697	46%
Humulin (Eli Lilly)	602,018	494,753	449,745	405,778	404,418	400,984	390,804	318,787	291,080	286,965	-42%
Combined US-Treated Patients	1,258,680	1,462,503	1,605,681	1,576,788	1,943,812	1,785,972	1,865,178	1,907,101	1,936,975	2,001,964	59%
Growth	-	16%	10%	-2%	23%	-8%	4%	2%	2%	3%	

Exhibit 17 (Continued)

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	Change 2005-2014
Annual US Sales without Price Increases ($mil)											
Lantus (Sanofi)	$846	$1,247	$1,489	$1,509	$1,939	$1,741	$1,849	$1,993	$2,055	$2,144	-
Apidra (Sanofi)	-	-	-	-	73	72	82	88	107	107	-
Humulin (Eli Lilly)	448	368	334	302	301	298	291	237	216	213	-
Combined US Sales ($mil)	$1,294	$1,615	$1,824	$1,810	$2,313	$2,111	$2,222	$2,318	$2,379	$2,465	-
Annual US Sales due to Price Increases ($mil)											
Lantus (Sanofi)	-	$81	$251	$510	$810	$1,098	$1,187	$2,206	$2,891	$3,686	-
Apidra (Sanofi)	-	-	-	-	4	10	2	11	41	74	-
Humulin (Eli Lilly)	-	0	31	79	102	173	297	355	461	500	-
Combined US Fraudulent Sales ($mil)	-	$81	$281	$589	$916	$1,281	$1,487	$2,572	$3,392	$4,260	-
Growth	-	-	247%	109%	56%	40%	16%	73%	32%	26%	
Est. Part D Prescription Share (%)	-	30%	30%	30%	30%	30%	30%	30%	30%	30%	
Part D Sales due to Pricing Fraud ($mil)											
Lantus (Sanofi)	-	$24	$75	$153	$243	$329	$356	$662	$867	$1,106	-
Apidra (Sanofi)	-	-	-	-	1	3	1	3	12	22	-
Humulin (Eli Lilly)	-	0	9	24	31	52	89	107	138	150	-
Combined Part D Fraudulent Sales ($mil)	-	$24	$84	$177	$275	$384	$446	$772	$1,018	$1,278	-
Growth	-	-	247%	109%	56%	40%	16%	73%	32%	26%	
Cumulative Part D Fraudulent Sales ($mil)											
Lantus (Sanofi)	-	$24	$100	$252	$495	$825	$1,181	$1,843	$2,710	$3,816	-
Apidra (Sanofi)	-	-	-	-	1	4	5	8	21	43	-
Humulin (Eli Lilly)	-	0	9	24	31	52	141	248	386	536	-
Cumulative Part D Fraudulent Sales ($mil)	-	$24	$109	$276	$527	$881	$1,327	$2,099	$3,116	$4,394	-
Growth	-	-	347%	154%	91%	67%	51%	58%	48%	41%	

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 18

Pfizer Products

Part D Direct BFSF Payment Fraud Estimates: 2007 to 2014

	2007	2008	2009	2010	2011	2012	2013	2014	Period Change
Lyrica	$1,048	$1,449	$1,504	$1,424	$1,514	$1,672	$1,963	$2,315	223%
Viagra	794	897	962	992	1,003	1,135	1,132	1,140	43%
Celebrex	1,719	1,819	1,697	1,580	1,597	1,745	1,933	1,735	10%
Chantix	-	-	386	330	326	313	343	377	-2%
Premarin	-	-	-	949	915	977	1,001	992	5%
Pristiq	-	-	77	405	474	493	540	553	618%
Relpax	-	-	-	189	193	219	218	244	29%
Combined US Sales ($mil)	$3,561	$4,165	$4,626	$5,869	$6,022	$6,554	$7,130	$7,356	138%
Growth	15%	17%	11%	27%	3%	9%	9%	3%	
Price Increases as % of US Growth	72%	73%	51%	-16%	340%	188%	149%	276%	87%
Manufacturer US Revenues/Patient ($)									
Lyrica	$1,325	$1,484	$1,618	$1,780	$1,916	$2,201	$2,490	$2,795	111%
Viagra	815	962	1,116	1,294	1,394	1,684	1,747	1,880	154%
Celebrex	1,535	1,643	1,725	1,811	1,935	2,226	2,545	2,502	82%
Chantix	-	-	1,122	1,279	1,450	1,574	1,885	2,064	84%
Premarin	-	-	-	892	999	1,218	1,400	1,590	78%
Pristiq	-	-	1,267	1,330	1,408	1,672	2,015	2,329	84%
Relpax	-	-	-	1,784	1,946	2,324	2,390	2,805	57%
Average Price ($)	$1,225	$1,363	$1,370	$1,453	$1,578	$1,843	$2,067	$2,281	99%
Estimated Annual US-Treated Patients									
Lyrica	790,731	976,153	929,546	800,093	790,236	759,502	788,399	828,167	53%
Viagra	973,949	932,451	862,086	766,354	719,593	673,958	647,915	606,281	-44%
Celebrex	1,119,542	1,107,168	983,724	872,287	825,154	783,823	759,524	693,487	-40%
Chantix	-	-	343,930	257,924	224,830	198,857	181,952	182,695	-47%
Premarin	-	-	-	1,064,475	915,549	801,836	715,097	624,007	-41%
Pristiq	-	-	60,790	304,513	336,566	294,930	268,046	237,468	291%
Relpax	-	-	-	105,951	99,168	94,239	91,201	86,998	-18%
Combined US-Treated Patients	2,884,223	3,015,773	3,180,077	4,171,597	3,911,097	3,607,145	3,452,133	3,259,104	18%
Growth	4%	5%	5%	31%	-6%	-8%	-4%	-6%	
Estimated Actual BFSFs (4% rate)									
Lyrica	$42	$58	$60	$57	$61	$67	$79	$93	223%
Viagra	32	36	38	40	40	45	45	46	43%
Celebrex	69	73	68	63	64	70	77	69	10%
Chantix	-	-	15	13	13	13	14	15	-2%
Premarin	-	-	-	38	37	39	40	40	5%
Pristiq	-	-	3	16	19	20	22	22	618%
Relpax	-	-	-	8	8	9	9	10	29%
Combined Actual BFSFs ($mil)	$142	$167	$185	$235	$241	$262	$285	$294	138%

Exhibit 18 (Continued)

	2007	2008	2009	2010	2011	2012	2013	2014	Change
Estimated Actual BFSFs/Patient ($)					-	-	-	-	-
Lyrica	$53	$59	$65	$71	$77	$88	$100	$112	111%
Viagra	33	38	45	52	56	67	70	75	154%
Celebrex	61	66	69	72	77	89	102	100	82%
Chantix	-	-	45	51	58	63	75	83	84%
Premarin	-	-	-	36	40	49	56	64	78%
Pristiq	-	-	51	53	56	67	81	93	84%
Relpax	-	-	-	71	78	93	96	112	57%
Average Actual BFSFs/Patient ($)	$49	$55	$58	$56	$62	$73	$83	$90	102%
Estimated Annual BFSFs w/o Price Increases (4% rate)									
Lyrica	$42	$52	$49	$42	$42	$40	$42	$44	
Viagra	$29	$28	$26	$23	$21	$20	$19	$18	
Celebrex	$61	$61	$54	$48	$45	$43	$42	$38	
Chantix	-	-	$15	$12	$10	$9	$8	$8	
Premarin	-	-	-	$38	$33	$29	$26	$22	
Pristiq	-	-	$3	$15	$17	$15	$14	$12	
Relpax	-	-	-	$8	$7	$7	$7	$6	
Total BFSFs w/o Price Increases ($mil)	$132	$140	$147	$185	$175	$162	$156	$149	
Estimated Part D Prescription Share (%)									
Lyrica	30%	30%	30%	30%	30%	30%	30%	30%	
Viagra	10%	10%	10%	10%	10%	10%	10%	10%	
Celebrex	35%	35%	35%	35%	35%	35%	35%	35%	
Chantix	15%	15%	15%	15%	15%	15%	15%	15%	
Premarin	30%	30%	30%	30%	30%	30%	30%	30%	
Pristiq	25%	25%	25%	25%	25%	25%	25%	25%	
Relpax	15%	15%	15%	15%	15%	15%	15%	15%	
Estimated Part D Fraudulent BFSFs ($, 4% rate)									
Lyrica	$0	$2	$3	$4	$6	$8	$11	$15	
Viagra	$0	$1	$1	$2	$2	$3	$3	$3	
Celebrex	$3	$4	$5	$5	$7	$9	$12	$11	
Chantix	-	-	$0	$0	$0	$1	$1	$1	
Premarin	-	-	-	$0	$1	$3	$4	$5	
Pristiq	-	-	$0	$0	$0	$1	$2	$3	
Relpax	-	-	-	$0	$0	$0	$0	$1	
Total Fraudulent Part D BFSFs ($mil)	$3	$7	$9	$12	$16	$25	$34	$38	
Cumulative Part D Fraudulent BFSFs ($, 4% rate)									
Lyrica	$0	$2	$3	$8	$13	$21	$32	$47	
Viagra	$0	$1	$1	$3	$5	$7	$10	$13	
Celebrex	$3	$4	$5	$10	$17	$26	$39	$50	
Chantix	-	-	$0	$0	$1	$1	$2	$3	
Premarin	-	-	-	$0	$1	$4	$9	$14	
Pristiq	-	-	$0	$0	$1	$2	$4	$6	
Relpax	-	-	-	$0	$0	$0	$1	$1	
Cum Fraudulent Part D BFSFs ($mil)	$3	$7	$9	$21	$38	$63	$96	$134	

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 19

Pfizer Products

Part D Sales Fraud Estimates: 2007 to 2014

	2007	2008	2009	2010	2011	2012	2013	2014	Period Change
Corporate-Reported US Sales ($mil)									
Lyrica	$1,048	$1,449	$1,504	$1,424	$1,514	$1,672	$1,963	$2,315	223%
Viagra	794	897	962	992	1,003	1,135	1,132	1,140	43%
Celebrex	1,719	1,819	1,697	1,580	1,597	1,745	1,933	1,735	10%
Chantix	-	-	386	330	326	313	343	377	-2%
Premarin	-	-	-	949	915	977	1,001	992	5%
Pristiq	-	-	77	405	474	493	540	553	618%
Relpax	-	-	-	189	193	219	218	244	29%
Combined US Sales ($mil)	$3,561	$4,165	$4,626	$5,869	$6,022	$6,554	$7,130	$7,356	138%
Growth	15%	17%	11%	27%	3%	9%	9%	3%	
Estimated Annual US-Treated Patients									
Lyrica	790,731	976,153	929,546	800,093	790,236	759,502	788,399	828,167	53%
Viagra	973,949	932,451	862,086	766,354	719,593	673,958	647,915	606,281	-44%
Celebrex	1,119,542	1,107,168	983,724	872,287	825,154	783,823	759,524	693,487	-40%
Chantix	-	-	343,930	257,924	224,830	198,857	181,952	182,695	-47%
Premarin	-	-	-	1,064,475	915,549	801,836	715,097	624,007	-41%
Pristiq	-	-	60,790	304,513	336,566	294,930	268,046	237,468	291%
Relpax	-	-	-	105,951	99,168	94,239	91,201	86,998	-18%
Combined US-Treated Patients	2,884,223	3,015,773	3,180,077	4,171,597	3,911,097	3,607,145	3,452,133	3,259,104	18%
Growth	4%	5%	5%	31%	-6%	-8%	-4%	-6%	
Manufacturer US Revenues/Patient ($)									
Lyrica	$1,325	$1,484	$1,618	$1,780	$1,916	$2,201	$2,490	$2,795	111%
Viagra	815	962	1,116	$1,294	$1,394	$1,684	$1,747	$1,880	154%
Celebrex	1,535	1,643	1,725	$1,811	$1,935	$2,226	$2,545	$2,502	82%
Chantix	962	1,030	1,122	$1,279	$1,450	$1,574	$1,885	$2,064	84%
Premarin	-	-	-	$892	$999	$1,218	$1,400	$1,590	78%
Pristiq	-	1,209	1,267	$1,330	$1,408	$1,672	$2,015	$2,329	84%
Relpax	-	-	-	$1,784	$1,946	$2,324	$2,390	$2,805	57%
Average Price ($)	$1,225	$1,363	$1,370	$1,453	$1,578	$1,843	$2,067	$2,281	99%
Annual US Sales without Price Increases ($mil)									
Lyrica	$1,048	$1,294	$1,232	$1,060	$1,047	$1,007	$1,045	$1,098	-
Viagra	722	691	639	568	533	499	480	449	-
Celebrex	1,535	1,518	1,349	1,196	1,131	1,075	1,041	951	-
Chantix	-	-	386	289	252	223	204	205	-
Premarin	-	-	-	949	816	715	638	556	-
Pristiq	-	-	77	386	426	374	340	301	-
Relpax	-	-	-	189	177	168	163	155	-
Combined US Sales ($mil)	$3,305	$3,503	$3,683	$4,637	$4,384	$4,060	$3,910	$3,715	-

Exhibit 19 (Continued)

	2007	2008	2009	2010	2011	2012	2013	2014	Period Change
Annual US Sales due to Price Increases ($mil)									
Lyrica	$0	$155	$272	$364	$467	$665	$918	$1,217	-
Viagra	72	206	323	424	470	636	652	691	-
Celebrex	184	301	348	384	466	670	892	784	-
Chantix	-	-	-	41	74	90	139	172	-
Premarin	-	-	-	-	99	262	363	436	-
Pristiq	-	-	-	19	48	119	200	252	-
Relpax	-	-	-	-	16	51	55	89	-
Combined US Fraudulent Sales ($mil)	$256	$662	$943	$1,232	$1,638	$2,494	$3,220	$3,641	-
Growth	-	158%	42%	31%	33%	52%	29%	13%	
								-	
Est Part D Prescription Share (%)									
Lyrica	30%	30%	30%	30%	30%	30%	30%	30%	-
Viagra	10%	10%	10%	10%	10%	10%	10%	10%	-
Celebrex	35%	35%	35%	35%	35%	35%	35%	35%	-
Chantix	15%	15%	15%	15%	15%	15%	15%	15%	-
Premarin	30%	30%	30%	30%	30%	30%	30%	30%	-
Pristiq	25%	25%	25%	25%	25%	25%	25%	25%	-
Relpax	15%	15%	15%	15%	15%	15%	15%	15%	-
Part D Sales due to Pricing Fraud ($mil)									
Lyrica	$0	$47	$82	$109	$140	$200	$275	$365	-
Viagra	7	21	32	42	47	64	65	69	-
Celebrex	64	105	122	134	163	235	312	274	-
Chantix	-	-	-	6	11	13	21	26	-
Premarin	-	-	-	-	30	79	109	131	-
Pristiq	-	-	-	5	12	30	50	63	-
Relpax	-	-	-	-	2	8	8	13	-
Total Part D Fraudulent Sales ($mil)	$72	$173	$236	$297	$405	$627	$841	$942	-
Growth	-	141%	37%	26%	36%	55%	34%	12%	
Cumulative Part D Fraudulent Sales ($mil)									
Lyrica	$0	$47	$128	$237	$377	$577	$852	$1,218	-
Viagra	7	28	60	103	149	213	278	347	-
Celebrex	64	170	292	426	589	824	1,136	1,411	-
Chantix	-	-	-	6	17	31	51	77	-
Premarin	-	-	-	-	30	108	217	348	-
Pristiq	-	-	-	5	17	47	97	160	-
Relpax	-	-	-	-	2	10	18	32	-
Total Part D Fraudulent Sales ($mil)	$72	$244	$480	$777	$1,182	$1,809	$2,650	$3,592	-
Growth	-	241%	97%	62%	52%	53%	46%	36%	

Source: Corporate reports, IMS, Redbook and Relator estimates.

Exhibit 20
Pfizer Products
Corporate-Reported Sales and IMS Trends

	2011	2011	2012	2013	2014	Change 2010-2014
Reported US Sales ($mil)						
Lyrica	$1,424	$1,514	$1,672	$1,963	$2,315	63%
Viagra	992	1,003	1,135	1,132	1,140	15%
Celebrex	1,580	1,597	1,745	1,933	1,735	10%
Chantix	330	326	313	343	377	14%
Premarin	949	915	977	1,001	992	5%
Pristiq	405	474	493	540	553	37%
Relpax	189	193	219	218	244	29%
Total Prescriptions						
Lyrica	9,601,114	9,482,837	9,114,028	9,460,785	9,938,009	4%
Viagra	9,196,247	8,635,115	8,087,490	7,774,985	7,275,375	-21%
Celebrex	10,467,444	9,901,844	9,405,874	9,114,285	8,321,847	-20%
Chantix	3,095,093	2,697,965	2,386,289	2,183,429	2,192,343	-29%
Premarin	12,773,702	10,986,586	9,622,031	8,581,158	7,488,084	-41%
Pristiq	3,654,157	4,038,793	3,539,162	3,216,550	2,849,616	-22%
Relpax	1,271,410	1,190,019	1,130,871	1,094,409	1,043,970	-18%
Pfizer-Reported Annual Cost of Therapy ($)						
Lyrica	$1,780	$1,916	$2,201	$2,490	$2,795	$1,016
Viagra	$1,294	$1,394	$1,684	$1,747	$1,880	$586
Celebrex	$1,811	$1,935	$2,226	$2,545	$2,502	$691
Chantix	$1,279	$1,450	$1,574	$1,885	$2,064	$784
Premarin	$892	$999	$1,218	$1,400	$1,590	$698
Pristiq	$1,330	$1,408	$1,672	$2,015	$2,329	$999
Relpax	$1,784	$1,946	$2,324	$2,390	$2,805	$1,021
Corporate-Reported Annual Change Price Per Prescription (%)						
Lyrica	-	8%	15%	13%	12%	57%
Viagra	-	8%	21%	4%	8%	45%
Celebrex	-	7%	15%	14%	-2%	38%
Chantix	-	13%	9%	20%	9%	61%
Premarin	-	12%	22%	15%	14%	78%
Pristiq	-	6%	19%	21%	16%	75%
Relpax	-	9%	19%	3%	17%	57%

Exhibit 20 (Continued)

	2011	2011	2012	2013	2014	2015YTD
AWP Price Changes (%)						
Lyrica	10%	9%	18%	19%	19%	19%
Viagra	16%	10%	18%	19%	18%	18%
Celebrex	5%	9%	18%	19%	21%	19%
Chantix	14%	18%	15%	14%	16%	16%
Premarin	9%	18%	18%	19%	16%	9%
Pristiq	5%	13%	15%	19%	19%	19%
Relpax	10%	13%	14%	9%	10%	11%
AWP Unit Prices ($)						
Lyrica (150mg)	$3.12	$3.40	$4.04	$4.83	$5.79	$6.94
Viagra (50-100mg)	$20.40	$22.49	$26.72	$32.01	$37.95	$45.45
Celebrex (200mg)	$4.43	$4.83	$5.74	$6.87	$8.42	$10.09
Chantix (1mg)	$2.69	$3.20	$3.69	$4.24	$4.94	$5.76
Premarin (0.3-1.25mg)	$2.02	$2.40	$2.85	$3.41	$3.97	$4.35
Pristiq (50mg)	$4.50	$5.11	$5.90	$7.07	$8.46	$10.14
Relpax (20 or 30mg)	$26.26	$29.64	$33.92	$37.04	$40.84	$45.45

Source: Corporate Reports, IMS and Redbook.

Exhibit 21

National Medicare Part D Enrollment: 2012

Plan Sponsor		*PBM*	*2012 Total Enrollment (000s)*	*% of 2012 Enrollment*
UnitedHealth Group	**PDP**	**UnitedHealth Group**	4,231.5	13.7%
UnitedHealth Group	**MA**	**UnitedHealth Group**	2,118.3	6.8%
Total UnitedHealth Group			6,349.8	20.5%
CVS Caremark	**PDP**	**Caremark CVS**	4,009.4	13.0%
Humana	**PDP**	**Humana**	2,998.0	9.7%
Humana	**MA**	**Humana**	1,840.3	5.9%
Total Humana			4,838.3	15.6%
Express Scripts	**PDP**	**Express Scripts**	1,689.7	5.5%
Other BlueCross/BlueShield	**MA**	**Express Scripts**	1,389.1	4.5%
Coventry	**PDP**	**Express Scripts**	1,577.3	5.1%
Coventry	**MA**	**Express Scripts**	204.5	0.7%
Envision	**PDP**	**Express Scripts**	383.6	1.2%
Total Express Scripts			5,244.2	17.0%
Anthem	**PDP**	**Anthem/Express Scripts**	535.8	1.7%
Anthem	**MA**	**Anthem/Express Scripts**	482.4	1.6%
Total Anthem			1,018.2	3.3%
Aetna	**PDP**	**Aetna/CVS Caremark**	480.6	1.6%
Aetna	**MA**	**Aetna/CVS Caremark**	350.0	1.1%
Total Aetna			830.6	2.7%
Cigna	**PDP**	**Cigna/Catamaran**	1,268.7	4.1%
Cigna	**MA**	**Cigna/Catamaran**	331.9	1.1%
Total Cigna			1,600.6	5.2%
Wellcare	**PDP**	**Wellcare/CVS Caremark**	874.3	2.8%
Wellcare	**MA**	**Wellcare/CVS Caremark**	122.7	0.4%
Total Wellcare			997.0	3.2%
All Others		**Various**	4,953.6	16.0%
Total			**30,931.4**	**100.0%**

Source: Pembroke Consulting Analysis of CMS data and Kaiser Family Foundation, Medicare Advantage 2012 Data Spotlight: Enrollment Market Update.

Exhibit 22
High Concentration of the US PBM and Specialty Pharmacy Markets: 2013
($billion)

US PBM Market:

Company	*Sales*	*Share of US Market*
Express Scripts	$96	27%
Caremark CVS	75	21%
Optum Rx[1]	34	10%
Prime	15	4%
Catamaran[2]	14	4%
Humana	13	4%
MedImpact	8	2%
Cigna	8	2%
All Others	24	7%
Total US PBM Sales	$287	82%
Total US Pharmaceutical Market	$350	100%

[1] Part of United Healthcare

[2] Catamaran was acquired by UnitedHealth Group in July 2015.

Source: IMS Health and CVS Investor Day Presentation dated 12/13/12, slide 18

US Specialty Pharmacy Market:

Company	*Sales ($bil)*	*Share of US Market*
Express Scripts	$2.4	30%
Caremark CVS	1.8	23%
Walgreens	0.8	10%
Diplomat Specialty	0.2	2%
Omnicare	0.2	2%
Other	2.6	33%
Total US Specialty Sales	$46.6	100%

Source: Pembroke Consulting, June 2012

Exhibit 23

Medicare Part D Specialty Drug Data: 2006-2008

Data for GAO Specialty Drug Report Dated January 2010

Price Concessions Negotiated by Seven Plan Sponsors[1]

For 20 Key Specialty Drugs

	Sponsors with Any Price Discounts			Annual Cost of Therapy After Price Concessions			Change 2006-	Annual Price Increase		Negotiated % Discount		
Drug/Manufacturer	2006	2007	2008	2006	2007	2008	2008	2007	2008	2006	2007	2008
Multiple Sclerosis												
Avonex (Biogen)	3	4	5	$16,764	$18,528	$22,608	35%	12%	23%	1.1%	2.2%	2.6%
Copaxone (Teva)	6	6	7	16,440	18,264	20,784	26%	13%	13%	6.2%	8.0%	7.2%
Inflammatory Conditions												
Humira (Abbvie)	6	7	7	$16,116	$16,896	$17,628	9%	6%	5%	6.1%	7.2%	8.2%
Enbrel (Amgen)	6	7	6	16,464	17,052	17,640	7%	4%	5%	2.0%	2.7%	3.7%
Anakinra (Amgen)	-	-	-	15,588	16,356	17,076	10%	5%	4%	0.0%	0.1%	0.1%
HIV												
Reyataz	5	6	6	$9,096	$9,384	$9,720	7%	4%	5%	2.7%	3.3%	5.0%
Truvada	0	0	0	9,180	9,780	10,572	15%	7%	8%	0.0%	0.0%	0.0%
Combivir	7	7	6	7,728	8,220	8,568	11%	6%	5%	3.3%	3.4%	3.6%
Kaletra	0	0	0	8,364	8,640	8,940	7%	3%	3%	0.0%	0.0%	0.0%
Cancer												
Tarceva (OSI/Roche)	0	0	0	$32,952	$37,236	$40,716	24%	13%	9%	0.0%	0.0%	0.0%
Gleevec (Novartis)	0	0	0	35,928	37,836	40,668	13%	5%	7%	0.0%	0.0%	0.0%
Pulmonary Hypertension												
Letairis (Gilead)	0	0	0	-	$49,200	$52,992	-	-	8%	-	0.0%	0.0%
Tracleer	0	0	0	41,796	48,780	53,076	27%	17%	9%	0.0%	0.0%	0.0%

[1] These Seven Sponsors accounted for 67% of Part D enrollment

Source: GAO-10-242, January 2010.

Exhibit 24

Medco Health Solutions, Inc.

SEC-Reported Manufacturer Rebate Data: 2003-2011

	2003	2004	2005	2006	2007	2008	2009	2010	2011	Growth 2003-2011
Rebate Trends										
Brand-Name Rebates ($mil)	$2,970	$3,005	$3,233	$3,417	$3,561	$4,447	$5,372	$5,806	$6,208	109.1%
Total Product Revenues	33,913	35,024	37,455	42,023	43,962	50,576	58,961	64,889	68,563	102.2%
Total Product Revenues & Rebates	$36,883	$38,029	$40,688	$45,440	$47,523	$55,023	$64,333	$70,695	$74,771	
Rebates as % of Total Revenues & Rebates	8.1%	7.9%	7.9%	7.5%	7.5%	8.1%	8.4%	8.2%	8.3%	
Medco Retained Rebates	$1,593	$1,324	$855	$670	$547	$806	$734	$724	$757	-52.4%
Retained Rebates as % of Total Rebates	53.6%	44.1%	26.4%	19.6%	15.4%	18.1%	13.7%	12.5%	12.2%	
Total Medco Gross Margin ($mil)	$1,522	$1,723	$1,943	$2,405	$2,945	$3,728	$4,027	$4,335	$4,622	203.7%
Growth Rate	-	13.2%	12.9%	23.9%	22.5%	26.6%	8.0%	7.7%	6.6%	
Retained Rebates as % of Total Gross Margin	104.7%	76.9%	44.0%	27.9%	18.6%	21.6%	18.2%	16.7%	16.4%	
% Formulary Rebates	49.6%	47.3%	50.8%	51.9%	50.1%	54.7%	78.7%	85.3%	87.0%	
% Performance/Market Share Rebates	50.4%	52.7%	49.2%	48.1%	49.9%	45.3%	21.3%	14.7%	13.0%	

Source: Medco 2003-2011 10K filings on file with the Securities and Exchange Commission (SEC).

Exhibit 25

Medco Health Solutions, Inc.: 2003-2011
Profitability Trends without Retained Rebates
Implies Astounding Increase in Generic Profitability

	2003	2004	2005	2006	2007	2008	2009	2010	2011	Cumulative 2003-2011
SEC-Reported Total Medco Gross Profit	$1,522	$1,723	$1,943	$2,405	$2,945	$3,728	$4,027	$4,335	$4,622	-
Medco Retained Rebates	$1,593	$1,324	$855	$670	$547	$806	$734	$724	$757	-
Gross Profits w/o Retained Rebates	-$71	$399	$1,088	$1,735	$2,398	$2,922	$3,293	$3,611	$3,865	$19,241

Source: Medco 2003-2011 10K filings on file with the Securities and Exchange Commission (SEC).

Exhibit 26
Medco Health Solutions, Inc.
Components of Revenue Growth: 2006-2011
Near Complete Dependence on Branded Price Increases

	2006	2007	2008	2009	2010	2011	Cumulative 2006-2011	Growth Contribution 2006-2011
Total Medco Revenues	$25,880	$26,424	$28,614	$36,596	$40,209	$41,907		
Net Volume Increase	1,925	1,660	3,676	6,106	3,929	1,591	$18,887	60.7%
Net Branded Price Increase	4,561	2,784	5,628	4,709	5,674	5,683	29,039	93.3%
Generic Impact	-1,720	-2,505	-2,690	-2,430	-3,675	-3,600	-16,620	-53.4%
Other	-198	-	-	-	-	-	-198	-0.6%
Total Annual Increase	$4,568	$1,939	$6,614	$8,385	$5,928	$3,674	$31,108	100.0%

Source: Medco 2006-2011 10K filings on file with the Securities and Exchange Commission (SEC).

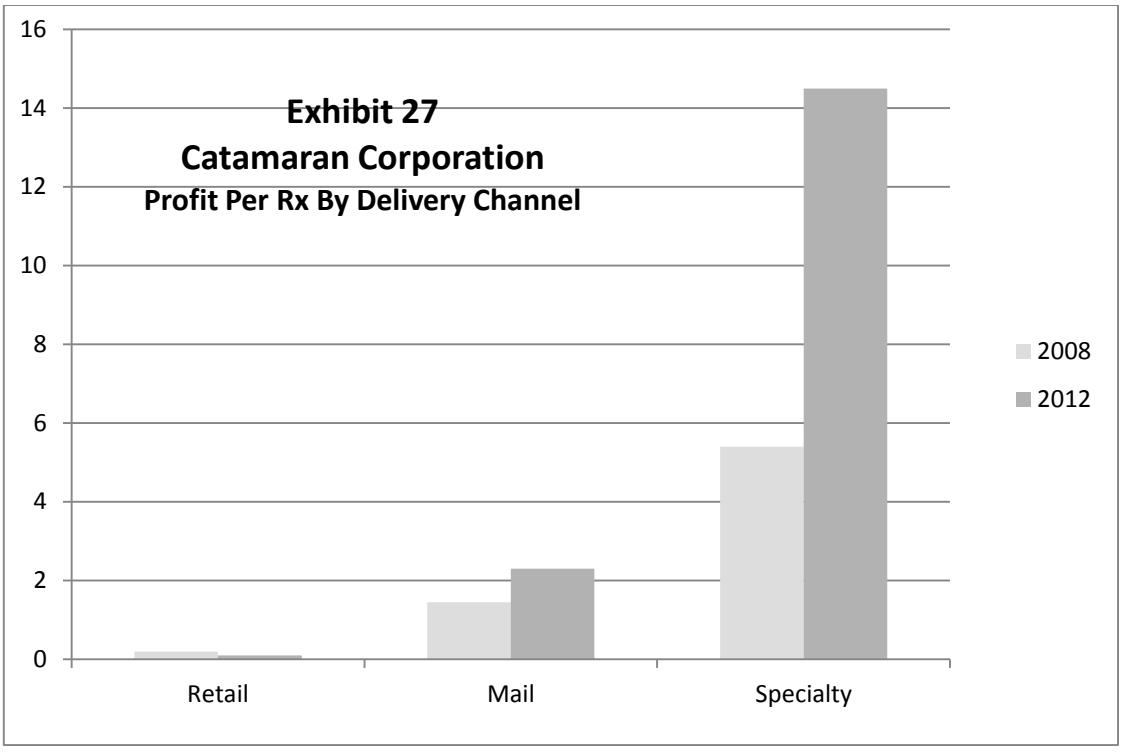
Exhibit 27
Catamaran Corporation
Profit Per Rx By Delivery Channel
16
14
12
10
8
6
4
2
0
Retail
Mail
Specialty
2008
2012

Exhibit 28
Express Scripts Drug Trend Reports
Components of Medicare Drug Spending Growth

	2010	2011	2012	2013	2014
Traditional Pharmaceuticals					
Cost	-2.2%	-2.6%	-2.6%	-3.7%	5.9%
Utilization	2.5%	3.6%	1.8%	3.7%	0.5%
Total Growth	0.3%	0.9%	-0.7%	0.0%	6.4%
Specialty Drugs					
Cost	9.8%	11.6%	26.8%	15.3%	34.3%
Utilization	2.9%	8.4%	-2.7%	-0.6%	11.6%
Total Growth	12.7%	20.0%	24.1%	14.7%	45.9%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2014.

Exhibit 29

Express Scripts Drug Trend Reports: 2010-2014

Top-Spending Medicare Part D Traditional Drug Categories

	2010	2011	2012	2013	2014	
All Traditional Drugs						
PMPY ($)	$2,165.70	$2,129.35	$1,908.70	$2,045.07	$2,262.41	
Cost	-2.2%	-2.6%	-2.6%	-3.7%	5.9%	
Utilization	2.5%	3.6%	1.8%	3.7%	0.5%	
Total Growth	0.3%	0.9%	-0.7%	0.0%	6.4%	
Price Increases as % of Growth	-	-	-	-	92.2%	
Utilization as % of Growth	-	-	-	-	7.8%	Contribution to 2010-2014 Growth
Diabetes						
PMPY ($)	$294.60	$319.00	$278.72	$270.62	$358.93	66.5%
Cost	3.3%	5.5%	10.6%	10.2%	21.5%	
Utilization	5.5%	5.1%	4.5%	4.2%	4.9%	
Total Growth	8.8%	10.7%	15.2%	14.5%	26.4%	
Price Increases as % of Growth	37.5%	51.4%	69.7%	70.3%	81.4%	
Utilization as % of Growth	62.5%	47.7%	29.6%	29.0%	18.6%	
High Cholesterol						
PMPY ($)	$190.68	$205.58	$209.58	$198.48	$205.70	
Cost	6.4%	-0.2%	-8.2%	-9.2%	-1.3%	
Utilization	-6.6%	4.4%	1.5%	4.4%	0.3%	
Total Growth	-2.0%	4.2%	-6.7%	-4.8%	-1.0%	
High Blood Pressure/Heart Disease						
PMPY ($)	$259.20	$226.65	$194.28	$182.88	$184.93	
Cost	-9.3%	-15.6%	1.7%	4.5%	-11.2%	
Utilization	3.1%	2.6%	-2.9%	-4.7%	0.1%	
Total Growth	-6.2%	-12.9%	-1.2%	-0.2%	-11.1%	
Mental/Neurologic Disorders						
PMPY ($)	$224.76	$201.15	$144.68	$168.15	$183.18	
Cost	9.4%	-7.4%	-19.3%	-10.5%	7.3%	
Utilization	1.1%	-0.3%	2.4%	-9.2%	-3.0%	
Total Growth	10.5%	-7.8%	-16.9%	-19.7%	4.2%	
Heartburn/Ulcer Disease						
PMPY ($)	$104.40	$87.00	$95.19	$107.67	$113.11	
Cost	-11.5%	-23.6%	-12.1%	-4.3%	-4.1%	
Utilization	4.0%	5.9%	7.7%	4.4%	0.0%	
Total Growth	-7.5%	-17.7%	-4.4%	0.1%	-4.1%	
Depression						
PMPY ($)	-	$69.89	$70.66	$85.12	$71.95	
Cost	-	-7.8%	0.2%	-0.3%	-20.2%	
Utilization	-	5.9%	4.7%	2.9%	1.5%	
Total Growth	-	-1.9%	4.9%	2.6%	-18.7%	

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2014.

Exhibit 30

Express Scripts Drug Trend Reports: 2010-2014

Top-Spending Traditional Medicare Part D Drugs

	2010	2011	2013	2014
Lantus (Sanofi, diabetes)				
PMPY ($)	-	-	$60.62	$77.17
Cost	-	-	21.1%	31.7%
Utilization	-	-	5.4%	-8.4%
Total Growth	-	-	26.5%	23.3%
Nexium (Astra Zeneca, ulcers)				
PMPY ($)	-	-	$66.51	$76.07
Cost	-	-	11.6%	12.7%
Utilization	-	-	-9.7%	-12.0%
Total Growth	-	-	1.9%	0.7%
Crestor (Astra Zeneca, cholesterol)				
PMPY ($)	$32.40	$42.74	$59.24	$70.25
Cost	-17.6%	11.1%	10.7%	12.5%
Utilization	32.6%	14.8%	-3.7%	-1.4%
Total Growth	15.0%	27.6%	7.0%	11.1%
Abilify Bristol-Myers, schizophrenia)				
PMPY ($)	-	-	$42.51	$51.17
Cost	-	-	11.7%	18.8%
Utilization	-	-	-15.5%	-1.8%
Total Growth	-	-	-3.8%	16.9%
Advair Diskus (Glaxo, asthma/COPD)				
PMPY ($)	$51.48	$54.48	$50.36	$50.23
Cost	-8.6%	6.6%	9.3%	7.6%
Utilization	16.9%	-2.5%	-10.6%	-11.2%
Total Growth	8.3%	3.9%	-1.3%	-3.6%
Spiriva (B. Ingelheim, asthma/COPD)				
PMPY ($)	-	$34.84	$44.06	$47.27
Cost	-	16.8%	8.0%	7.2%
Utilization	-	6.0%	-5.2%	-4.5%
Total Growth	-	23.8%	2.9%	2.7%

Exhibit 30 (Continued)

	2010	2011	2013	2014
Namenda XR (Watson, Alzheimer's)				
PMPY ($)	-	-	$0.28	$44.52
Cost	-	-	13.6%	16.3%
Utilization	-	-	0.1%	0.1%
Total Growth	-	-	13.7%	26.4%
Namenda (Watson, Alzheimer's)				
PMPY ($)	-	-	$35.30	-
Cost	-	-	12.6%	-
Utilization	-	-	-9.3%	-
Total Growth	-	-	3.3%	-
Januvia (Merck, diabetes)				
PMPY ($)	-	$30.56	$32.24	$40.88
Cost	-	8.6%	14.0%	17.7%
Utilization	-	18.6%	2.2%	3.4%
Total Growth	-	28.8%	16.1%	21.1%
Cymbalta (Eli Lilly, depression)				
PMPY ($)	-	-	$41.39	-
Cost	-	-	18.2%	-
Utilization	-	-	1.6%	-
Total Growth	-	-	19.7%	-
Levemir (Novo Nordisk, diabetes)				
PMPY ($)	-	-	-	$32.87
Cost	-	-	-	47.7%
Utilization	-	-	-	60.5%
Total Growth	-	-	-	108.2%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2014.

Exhibit 31
Express Scripts Drug Trend Reports: 2010-2014
Top-Spending Medicare Part D Specialty Drug Categories

	2010	2011	2012	2013	2014	Average 2010-14
All US Medicare Specialty Drugs						
PMPY ($)	$198.60	$306.87	$353.62	$496.68	$724.94	
Cost	9.8%	11.6%	26.8%	15.3%	34.3%	19.6%
Utilization	2.9%	8.4%	-2.7%	-0.6%	11.6%	4.9%
Total Growth	12.7%	20.0%	24.1%	14.7%	45.9%	
Price Increases as % of Growth	77.2%	58.0%	111.2%	104.1%	74.7%	85.0%
Utilization as % of Growth	22.8%	42.0%	-11.2%	-4.1%	25.3%	
Multiple Sclerosis						
PMPY ($)	$24.00	$32.10	$51.68	$85.18	$106.09	
Cost	11.4%	14.1%	18.2%	14.1%	12.1%	14.0%
Utilization	9.6%	20.3%	8.5%	5.7%	15.9%	
Total Growth	21.0%	34.4%	26.7%	19.8%	27.9%	
Price Increases as % of Growth	54.3%	41.0%	68.2%	71.2%	43.4%	
Utilization as % of Growth	45.7%	59.0%	31.8%	28.8%	57.0%	
Inflammatory Conditions						
PMPY ($)	$34.44	$38.52	$47.69	$62.28	$86.95	
Cost	6.7%	8.3%	13.0%	13.6%	17.8%	11.9%
Utilization	3.4%	13.2%	7.4%	0.1%	12.8%	
Total Growth	10.1%	21.5%	20.4%	13.7%	30.7%	
Price Increases as % of Growth	66.3%	38.6%	63.7%	99.3%	58.0%	65.2%
Utilization as % of Growth	33.7%	61.4%	36.3%	0.7%	41.7%	
Cancer						
PMPY ($)	$64.80	$78.53	$108.39	$152.68	$206.97	
Cost	10.7%	14.7%	21.1%	16.3%	12.6%	15.1%
Utilization	5.8%	12.5%	11.8%	17.3%	24.6%	
Total Growth	16.5%	27.2%	32.8%	33.6%	37.2%	
Price Increases as % of Growth	64.8%	54.0%	64.3%	48.5%	33.9%	53.1%
Utilization as % of Growth	35.2%	46.0%	36.0%	51.5%	66.1%	
Hepatitis C						
PMPY ($)	$3.00	$7.78	$10.83	$9.93	$106.02	
Cost	-5.2%	14.7%	46.9%	-	922.3%	
Utilization	-20.9%	12.5%	63.5%	-	145.2%	
Total Growth	-26.2%	27.2%	110.4%	-	1067.5%	
Price Increases as % of Growth	-	54.0%	42.5%	-	86.4%	
Utilization as % of Growth	-	46.0%	57.5%	-	13.6%	

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2014.

Exhibit 32

Express Scripts Drug Trend Reports: 2010-2014

Top-Spending Specialty Medicare Part D Drugs

	2010	2011	2013	2014
Sovaldi (Gilead, Hepatitis C)				
PMPY ($)	-	-	-	$66.20
Cost	-	-	-	476.7%
Utilization	-	-	-	15624.4%
Total Growth	-	-	-	16101.1%
Revlimid (Celgene, multiple myeloma)				
PMPY ($)	$15.60	$18.79	$41.37	$47.78
Cost	1.4%	5.1%	6.5%	6.3%
Utilization	26.6%	10.8%	10.1%	14.1%
Total Growth	27.9%	16.4%	16.6%	20.3%
Copaxone (Teva, multiple sclerosis)				
PMPY ($)	$9.96	$13.50	$36.15	$36.91
Cost	21.7%	19.0%	12.1%	-2.2%
Utilization	14.9%	9.5%	-0.7%	10.2%
Total Growth	36.6%	30.3%	11.4%	8.0%
Enbrel (Amgen, inflammatory)				
PMPY ($)	$16.20	$17.85	$27.18	$33.46
Cost	4.7%	8.4%	12.6%	17.0%
Utilization	-3.7%	9.1%	-7.1%	3.4%
Total Growth	0.9%	18.3%	5.5%	20.4%
Humira (Abbvie, inflammatory)				
PMPY ($)	$13.08	$0.10	$24.89	$33.17
Cost	6.9%	9.2%	13.5%	17.6%
Utilization	4.2%	12.7%	3.1%	6.4%
Total Growth	11.1%	23.1%	16.6%	24.0%
Gleevec (Novartis, leukemia)				
PMPY ($)	$10.80	$12.97	$23.57	$29.31
Cost	12.3%	18.2%	13.1%	20.4%
Utilization	5.0%	4.3%	0.1%	6.0%
Total Growth	17.3%	23.3%	13.2%	26.4%
Zytiga (JNJ, prostate cancer)				
PMPY ($)	-	-	$13.43	$21.05
Cost	-	-	20.8%	14.2%
Utilization	-	-	61.7%	39.9%
Total Growth	-	-	82.4%	54.1%
Avonex (Biogen, multiple sclerosis)				
PMPY ($)	-	$7.45	$16.81	$17.66
Cost	-	13.2%	13.0%	11.6%
Utilization	-	28.4%	-1.0%	-4.4%
Total Growth	-	45.3%	12.0%	7.2%

Source: Express Scripts Drug Trend and Specialty Drug Trend Reports, 2010-2014.

Exhibit 33
Medicare Part D Spending: Share of Program Spending 2006 to 2014
In Private Part D Plans

	All Beneficiaries				
Program Year	Total Enrollment (millions)	Direct Subsidy Per Beneficiary ($)	Annual Program Direct Subsidies ($bil)	Re-Insurance Subsidy Per Beneficiary ($)	Annual Program Re-insurance Subsidies ($bil)
2006	20.3	$867	$17.6	$297	$6.0
2007	24.3	$744	$18.1	$330	$8.0
2008	25.8	$687	$17.7	$366	$9.4
2009	26.9	$702	$18.9	$375	$10.1
2010	28.0	$705	$19.7	$399	$11.2
2011	29.5	$681	$20.1	$465	$13.7
2012	31.8	$654	$20.8	$486	$15.5
2013	35.8	$567	$20.3	$535	$19.2
2014	37.8	$496	$18.7	$735	$27.8
2006-2014	86%	-43%	7%	147%	361%

	Low-Income Beneficiaries				
Program Year	LIS Enrollment (millions)	LIS Subsidy Per Beneficiary ($)	Annual Program LIS Subsidies ($bil)	Total Part D Reimbursement ($bil)	State Transfers ($bil)
2006	8.3	$1,817	$15.1	$38.7	$3.6
2007	9.2	$1,820	$16.7	$42.8	$7.0
2008	9.7	$1,856	$18.0	$45.2	$7.0
2009	10.0	$1,955	$19.6	$48.5	$7.5
2010	10.4	$2,020	$21.0	$51.9	$4.5
2011	10.6	$2,093	$22.2	$56.0	$6.5
2012	11.0	$2,045	$22.5	$58.7	$8.3
2013	11.5	$2,023	$23.3	$62.7	$8.7
2014	11.8	$2,060	$24.3	$70.8	$8.7
2006-2014	42%	13%	61%	83%	142%

Source: 2015 Annual Report from the Medicare Trustees.

Exhibit 34

"First Ever" Fair Market Value of Bona Fide Service Fees Conference

October 7-8, 2013, Philadelphia, PA

Presenter/Attendee List

Name	Title	Phone
Presenters (in chronological order)		
Tom Evegan	Senior Director, Commercial Contracting at Compliance Implementation Systems (CIS)	484-445-7200
John Shakow	Partner, King & Spalding	202-626-5523
Mark Linver [1]	Managing Director, Huron Consulting Group	312-583-8700
Stephanie Gilson	Assistant General Counsel, Johnson & Johnson	732-524-0400
Christopher Jackson	Corporate Attorney, Otsuka American Pharmaceuticals, Inc.	609-249-7292
Donna White	Senior Director, Contracts and Compliance at Cornerstone Therapeutics	609-409-7050
Joseph Metro	Partner, Reed Smith LLP	202-414-9284
Mark Dewyngaert, Ph.D.	Managing Director, Huron Consulting Group	312-583-8700
Michael Hepburn[2]	Senior Director, Government Contract Compliance at Janssen Pharmaceuticals, Inc.	908-927-2415
Doris Chern[2]	Senior Manager, Pricing Strategy and FMV at Janssen Pharmaceuticals, Inc.	908-927-2416
Jim Abrams	Director, Government Pricing and Reporting at Mylan Pharmaceuticals	304-598-5430
Trevor L. Wear	Senior Associate, Sidley Austin, LLP	312-853-7101
Julie DeLong, CFA	Director, Valuation and Financial Risk Management at Navigant Consulting, Inc.	404-602-5021
Isabel P. Dunst	Partner, Hogan Lovells US LLP	202-637-5818
John Moose, MBA, CPA, ABV	Project Leader, Huron Consulting Group	312-583-8700
Other Attendees		
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[1] Mark Linver did not attend the conference; his presentation was given by his colleague, Mark Dewyngaert

[2] Janssen Pharmaceuticals is a division of Johnson & Johnson

Source: CBI conference agenda and attendee poster from conference, Corporate websites.

Exhibit 35

Merck/Medco Merger - Quick Turnaround in Protecting Key Brand Drug Franchises

Combined Retail and Mail Order Prescriptions

Market Share as Percent of New Prescriptions

	Therapeutic Category Market Share				Yr/Yr New Rx Growth	
Products	**Nov 1992**	**Nov 1993**	**March 1994**	**April 1994**	**Nov 1993**	**Mar 1994**
Vasotec	35.3%	32.1%	31.3%	31.1%	4.2%	4.0%
Vasoretic	3.3	3.0	3.0	3.0	3.3	4.8
Prinivil	8.8	7.8	10.0	9.7	1.3	35.0
Prinzide	1.6	1.4	1.6	1.7	2.4	23.2
All Merck ACE Inhibitors	49.0	44.4	45.9	45.4	3.6	10.1
Entire ACE Inhibitor Market	-	-	-	-	14.4	14.0
Mevacor	41.0%	34.6%	33.9%	33.3%	0.2%	3.1%
Zocor	8.3	13.1	14.7	14.9	86.8	79.7
All Merck Cholesterol - Lowering	49.3	47.6	48.6	48.3	14.8	18.3
All HMG-CoA Agents	61.0	65.6	67.0	66.7	27.7	22.6
Entire Cholesterol-Lowering Mkt	-	-	-	-	18.8	11.9

Source: IMS Health.

Exhibit 36

Medicare Part D Pricing Across Plans and Geographies
Identical Pricing Suggests Near Complete Collusion
PlanPrescriber.com Search as of 9/3/2013

		Avg. Annual Part D Drug Cost by Location		
	Dosage	New York	Minneapolis	Los Angeles
Zip Code		11935	48322	91331
Number of Medicare PDP Plans		25	26	27
Multiple Sclerosis				
Avonex (Biogen)	30 mcg per week	$46,851	$46,851	$46,851
Copaxone (Teva)	20 mg per day	$49,904	$49,904	$49,904
Rebif (Pfizer)	22 mcg three times a week	$41,567	$41,567	$41,567
Rheumatoid Arthritis				
Enbrel (Amgen)	25 mg twice a week	$25,881	$25,881	$25,881
Humira (Abbvie)	40 mg every two weeks	$25,637	$25,637	$25,637
Cancer				
Gleevec (Novartis)	400 mg once a day	$72,783	$72,783	$72,783
Sprycel (Bristol Myers)	100 mg once a day	$102,329	$102,329	$102,329
Tasigna (Novartis)	300 mg twice a day	$102,300	$102,300	$102,300
Hepatitis C				
Incivek (Vertex)	750 mg TID	-	-	-
Victrelis (Merck)	800 mg TID	-	-	-
Pegasys (Roche)	180 mcg per week	-	-	-
PegIntron (Merck)	80 mcg per week	-	-	-
Diabetes				
Victoza (Novo Nordisk)	0.6 mg QD	$3,810	$3,810	$3,810
Bydureon (Bristol Myers)	2 mg per week	$4,315	$4,315	$4,315
Januvia (Merck)	25mg QD	$2,817	$2,817	$2,817
Onglyza (BMY/AZN)	2.5 mg QD	$2,816	$2,816	$2,816
Tradjenta (BI)	5 mg QD	$2,806	$2,806	$2,806

Source: Ehealth, PlanPrescriber.com

Exhibit 37

Breakdown of Los Angeles Part D PDP Plans

Highly Concentrated PBM Shares

PlanPrescriber.com Search as of 9/3/2013

PBM	Number of Plans	Share of Plans
Express Scripts	12	44.4%
CVS Caremark	5	18.5%
United Healthcare	3	11.1%
Humana	3	11.1%
Wellcare	2	7.4%
Catamaran	2	7.4%
Total Plans	27	100.0%

Source: Ehealth, PlanPrescriber.com

Exhibit 38

Comparison of Los Angeles Medicare Part D PDP Plans - Zip Code 91331

Identical Pricing for Defendant MS Drugs Across All Part D Plans

PlanPrescriber.com Search as of 9/3/2013

			Average Annual Part D Drug Cost by Plan ($)				
Plan	Sponsor	PBM	Avonex	Copaxone	Rebif	Enbrel	Gleevec
1) Blue Cross MedicareRx Plus	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
2 Blue Cross MedicareRx Gold	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
3) United American - Enhanced	United American	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
4) Express Scripts Medicare - Value	Express Scripts	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
5) Express Scripts Medicare - Choice	Express Scripts	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
6) Wellcare Classic	Wellcare	Wellcare	$46,851	$49,904	$41,567	$25,881	$72,783
7) Humana Walmart-Preferred Rx	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
8) AARP Medicare Rx Saver Plus	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
9) Wellcare Extra	Wellcare	Wellcare	$46,851	$49,904	$41,567	$25,881	$72,783
10) Human Enhanced	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
11) Reader's Digest Value Rx	HealthMarkets	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
12) Aetna CVS PDP	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
13) Blue Cross MedicareRx Standard	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
14) AARP Medicare Rx Saver Preferred	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
15) Cigna Medicare Rx Plan One	Cigna	Catamaran	$46,851	$49,904	$41,567	$25,881	$72,783
16) AARP Medicare Rx Enhanced	United Healthcare	United Healthcare	$46,851	$49,904	$41,567	$25,881	$72,783
17) Humana Complete	Humana	Humana	$46,851	$49,904	$41,567	$25,881	$72,783
18) Aetna Medicare Rx Premier	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
19) Blue Shield Medicare Basic Plan	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
20) Blue Shield Medicare Enhanced	Anthem	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
21) United American Select	United American	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
22) EnvisionRxPlus Silver	Envision Insurance	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
23) EnvisionRxPlus Gold	Envision Insurance	Express Scripts	$46,851	$49,904	$41,567	$25,881	$72,783
24) HealthSpring PDP	Cigna	Catamaran	$46,851	$49,904	$41,567	$25,881	$72,783
25) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
26) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783
27) First Health Part D Value Plus	Aetna	CVS Caremark	$46,851	$49,904	$41,567	$25,881	$72,783

Source: EHealth, PlanPrescriber.com

Exhibit 39

Key PBM Specialty Pharmacy Services

Nearly Identical Services Across Major PBMs - Little Targeted at Manufacturers

	Express Scripts	CVS/Caremark	Catamaran
Patients	Express shipping to home	Express shipping to home	Express shipping to home
	Education/Instruction materials	Education/Instruction materials	Education/Instruction materials
	Injection training	Injection training	Injection training
	Refill reminders	Refill reminders	Refill reminders
	On call 24/7 pharmacist	On call 24/7 pharmacist	On call 24/7 pharmacist
	Online community support	Online community support	Online community support
	Insurance counseling/assistance	Insurance counseling/assistance	Insurance counseling/assistance
	Care Coordination with physician office	Care Coordination with physician office	Care Coordination with physician office
	Welcome packet	Adherence check-ups via outreach calls	Initial phone consultation with firs Rx
	Monthly care coordinator call		Regular follow-up
Physicians	Express shipping to office	Express shipping to office	Express shipping to office
	Broad distribution network	Broad distribution network	Broad distribution network
	Prior authorization assistance	Prior authorization assistance	Easy Rx ordering/dedicated phone lines
	Specialty medication referral forms	Benefit verification/coordination	Prior authorization assistance
	Convenient ordering options	Vigilant monitoring with MD alerts	
Plan Sponsors	Coordinated account management	Help clients gain "control"	Broad drug access
	- Day-to-day specialty support	Strong patient support	Fast delivery
	- Regular strategic consultation	Increased adherence/minimize waste	Refill reminders
	Customized Reporting	Broad specialty drug access	Prior authorization assistance
	- Cost and dispensing reporting	Utilization management	Centralized technology
	- Utilization and outcome reporting		Share real-time data
	- Provider treatment and dispensing patterns		Clinical expertise/guidelines
	- Adherence and compliance reporting		
	- Plan benchmarking		
	Strategic Communication		
	- Outbound calls to patients		
	Continuous Quality Management		
	- Client satisfaction surveys		
	Patient satisfaction surveys		
	- Annual reviews		
	- Quarterly reports		
	- Clinical management reports		
	- Annual strategic planning		
Manufacturers	None Listed	None Listed	Ensuring patient safety
			Achieving optimal product utilization
			Patient education/injection teaching
			Maintaining profitability
			REMS programs

Source: Express Scripts, CVS Caremark and Catamaran websites.

Exhibit 40

Medicare Part D Prescription Drug Event (PDE) Cost Data

Key Fields Implicated in Service Fee Fraud

Field #	Data Element	Field Description	Service Fee Fraud Impact
26	**Catastrophic Coverage Code**	This field indicates that a beneficiary has reached the out-of-pocket threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.	Escalating Reinsurance Subsidies due to both earlier and greater number of non-LIS beneficiaries exceeding Out-Of-Pocket annual limits; After threshold, CMS covers 80%, plan sponsor 15% and non-LIS beneficiary 5%; potential for significant fraud in handling of PBM Defendant 15% cost-sharing portion.
27	**Ingredient Cost Paid**	This field indicates that a beneficiary has reached the out-of-pocket threshold or attachment point. At this point, catastrophic coverage provisions begin, namely reinsurance and reduced beneficiary cost sharing.	Fraudulently escalated end-user drug price due to service fee fraud; field only includes end-user price, not price paid by PBM and/or plan sponsor from manufacturer.
30	**Gross Drug Cost Below Out-of-Pocket Threshold (GDCB)**	This field represents the gross drug cost paid to the pharmacy below the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a positive dollar amount. For claims above the attachment point, this field will contain a zero dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 31 (GDCA).	Due to fraudulent price increases, non-LIS beneficiaries pay greater Out-Of-Pocket amounts and reach the Catastrophic level sooner and more frequently.
31	**Gross Drug Cost Above Out-of-Pocket Threshold (GDCA)**	This field represents the gross drug cost paid to the pharmacy above the Out-of-Pocket threshold for a given PDE for a covered drug. For claims received prior to a beneficiary reaching the attachment point, this field will contain a zero dollar amount. For claims above the attachment point, this field will contain a positive dollar value. For a claim on which the attachment point is reached, there is likely to be a positive dollar amount in this field and there will be a positive dollar amount in field 30 (GDCB).	Fraudulently escalated end-user drug prices increased the Catastrophic cost burden on both CMS and non-LIS beneficiaries; fraudulently elevated plan bids, Reinsurance Subsidies and catastrophic reconciliation payments.

Exhibit 40 (Continued)

Medicare Part D Prescription Drug Event (PDE) Cost Data

Key Fields Implicated in Service Fee Fraud

Field #	Data Element	Field Description	Service Fee Fraud Impact
32	**Patient Pay Amount**	This field lists the dollar amount the beneficiary paid that is not reimbursed by a third party (e.g., copayments, coinsurance, deductible or other patient pay amounts). This amount contributes to a beneficiary's TrOOP only when it is a payment for a covered drug. Payments made by the beneficiary or family and friends shall also be reported in this field. Other third party payments made on behalf of a beneficiary that contribute to TrOOP shall be reported in field 33 (Other TrOOP Amount) or field 34 (Low-Income Cost-Sharing Amount, LICS) and payments that do not contribute shall be reported in field 35 (Patient Liability Reduction due to Other Payer Amount.	Fraudulently high drug prices lead to increased Out-Of-Pocket costs for non-LIS and partial LIS beneficiaries, especially given typical 25-30% co-insurance requirements for many specialty drugs; greatly increased need for manufacturer-funded and independent Patient Assistance Programs (PAPs).
33	**Other True Out-of-Pocket (TrOOP) Amount**	This field records all qualified third party payments that contribute to a beneficiary's TrOOP, except for the Low-Income Cost Sharing (LICS) and Patient Pay Amount. Examples include payments made on behalf of a beneficiary by a qualified State Pharmacy Assistance Program, charities or other TrOOP-eligible parties.	Massive escalation in Other TrOOP Amounts from manufacturer-funded PAPs for non-LIS beneficiaries; potential path of fraudulent payments from manufacturers to PBMs via TrOOP administration.
34	**Low-Income Cost-Sharing Subsidy Amount (LICS)**	This field contains plan-reported LICS amounts per drug event so that CMS systems can reconcile prospective LICS payments made to plans with actual LICS amounts incurred by the plan at the Point of Sale.	The fee fraud and associated massive drug price inflation leads to fraudulent Direct, LIS Subsidy and reconciliation payments to plan sponsors for LIS beneficiaries, as well as fraudulent annual Subsidy estimates in plan bids.
35	**Patient Liability Reduction due to Other Payer Amount (PLPRO)**	This field takes into account coordination of benefits that result I reduced patient liability, excluding TrOOP-eligible payers; examples include group health plans, Worker's Compensation and government programs (e.g., VA, Tricare).	Potential fraudulent overpayment by other payers helping to pay for the fraudulent excessive drug costs due to fee fraud.
36	**Covered D Plan Paid Amount (CPP)**	This field contains the net amount the plan paid for standard benefits (covered Part d drugs).	Standard costs of all Part D plans escalated by the excessive Manufacturer Defendant drug costs.

Source: CMS.

Exhibit 41

Medicare Part D Catastrophic Drug Spending

Fast Rising Drug Costs and Plan Sponsor Cost-Sharing Burden

($billion)

Aggregate Part D Program:

	Annual Reinsurance Subsidies	Annual Catastrophic Spending	Annual Sponsor Catastrophic Cost-Sharing (15%)
2006	$6.0	$7.5	$1.1
2007	8.0	10.0	1.5
2008	9.4	11.8	1.8
2009	10.1	12.6	1.9
2010	11.2	14.0	2.1
2011	13.7	17.1	2.6
2012	15.5	19.4	2.9
2013	19.2	24.0	3.6
2014	27.8	34.8	5.2
Cumulative 2006-2014	**$74.0**	**$92.5**	**$13.9**

Source: 2015 Medicare Trustees Report.

Exhibit 42

Comparison of Approved US Anti-TNF Biologic Therapies

	Humira	Enbrel	Cimzia	Simponi
Company/Year of US Launch:	AbbVie (2002)	Amgen (1998)	UCG Group (2008)	Johnson & Johnson (2009)
Molecule Name:	adalimumab	etanercept	certolizumab pegol	golimumab
Maintenance Dosage:	40 mg every other week	50 mg once weekly	400 mg every four weeks	50 mg once a month
Mode of Delivery	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection	Subcutaneous injection
FDA-Approved Indication:	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Adult Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Plaque Psoriasis	Rheumatoid Arthritis, Polyarticular Juvenile Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis	Crohn's Disease, Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis	Rheumatoid Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Ulcerative Colitis
Monotherapy Rh Arthritis Clinical Data:				
ACR20 vs. Placebo at 6 months[1,2]	46-53% vs. 19%	59% vs. 11%	46% vs. 9%	31% vs. 16%
ACR50 vs. Placebo	22-35% vs. 8%	40% vs. 5%	23% vs. 4%	16% vs. 4%
ACR70 vs. Placebo	12-18% vs. 2%	15% vs. 1%	6% vs. 0%	9% vs. 2%
Side Effects vs. Placebo:	Upper respiratory infections, sinusitis, abdominal pain, headache, rash	Infections, upper respiratory infections, injection site reaction	Upper respiratory infections, sinusitis, abdominal pain, headache, rash	At 2 year, 25% of 0.25mg dose Betaseron patients were exacerbation-free vs. 16% for placebo patients.
Safety Warning:	Serious infections, including tuberculosis, bacterial sepsis, fungal infections; Malignancy, including lymphoma.	Serious infections, including tuberculosis, bacterial sepsis, fungal infections; Malignancy, including lymphoma.	Serious infections, including tuberculosis, bacterial sepsis, fungal infections; Malignancy, including lymphoma.	Serious infections, including tuberculosis, bacterial sepsis, fungal infections; Malignancy, including lymphoma.

1 ACR20-700: American College of Rheumatology criteria for drug benefit - ACR20 means that a person's rheumatoid arthritis has improved by 20%.

2 The Simponi ACR data is in combination with other DMARDs, for patients previously-treated with other anti-TNF agents.

Source: FDA approved Prescribing Information labels for each drug.

Exhibit 43

Comparison of US-Approved First-Line CML TKI Drugs

	Gleevec	**Sprycel**	**Tasigna**
Company/Yr of US Launch:	**Novartis (2001)**	**Bristol Myers (2006)**	**Novartis (2007)**
Molecule Name:	**imatinib**	**dasatinib**	**nilotinib**
Dosage:	**400-600 mg once daily**	**100mg once daily**	**300 mg twice daily**
Mode of Delivery	**Oral**	**Oral**	**Oral**
FDA-Approved Indication:	**Adult and Pediatric CML, including newly-diagnosed and relapsed; CML in chronic, blast or accelerated phase; Kit-positive unresectable/metastatic Gastrointestinal Stromal Tumors (GIST).**	**Newly-diagnosed Adult CML; Treatment of CML in patients resistant or intolerant to Gleevec.**	**Newly-diagnosed Adult CML; Treatment of CML in patients resistant or intolerant to Gleevec.**
First-Line Efficacy:			
Long-term Efficacy:	**81% progression-free survival at 84 months**	**-**	**-**
FDA-Approved Data vs. Gleevec:	**-**	**Sprycel found to have superior major molecular response (MMR) to Gleevec at 1 and 2 years; In chronic phase, Sprycel had a high response rate in patients resistant or intolerant to Gleevec.**	**Tasigna found to have superior major molecular response (MMR) to Gleevec at 1 and 2 years; In chronic phase, Tasigna had a 51% response rate in patients resistant or intolerant to Gleevec.**
Side Effects:	**Edema, fluid retention, nausea, vomiting, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, abdominal pain.**	**Convenient oral dosing.**	**Rash, pruritis, alopecia, dry skin, nausea, vomiting, abdominal pain, musculoskeletal pain, diarrhea, fatigue.**
FDA Safety Warnings:	**Edema, severe fluid retention, cytopenias, severe congestive heart failure, severe hepatotoxicity, hemorrhage, gastrointestinal perforation, cardiogenic shock.**	**Myelosupression, bleeding, fluid retention, QT prolongation, cardiac dysfunction, pulmonary artery hypertension, embryo-fetal toxicity.**	**FDA "black box" warning: QT prologation and sudden death, myelosupression, cardiac/vascular events, pancreatitis, hepatoxicity, drug interactions, embryo-fetal toxicity.**

Source: FDA approved Prescribing Information labels for each drug.